2014-1648

United States Court of Appeals for the Federal Circuit

ANTARES PHARMA, INC.,

Plaintiff – Appellant,

v.

MEDAC PHARMA INC., and MEDAC GMBH,

Defendants – Appellees.

Appeal from the United States District Court for the District of Delaware In Case No. 1:14-cv-00270 Judge Sue L. Robinson

NON-CONFIDENTIAL BRIEF FOR PLAINTIFF-APPELLANT ANTARES PHARMA, INC.

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JULY 25, 2014

CERTIFICATE OF INTEREST

I, Imron T. Aly, Counsel for Plaintiff-Appellant Antares Pharma, Inc., certify the following:

1. The full name of every party or *amicus* represented by me is:

Antares Pharma, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

The party named in the caption is the real party in interest.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Antares Pharma, Inc. is a publicly traded company. It has no parent corporation and no publicly traded company owns more than 10 percent or more of its stock.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Imron T. Aly, Richard Hoskins, Sailesh K. Patel, Joel M Wallace of Schiff Hardin LLP; Ahmed Riaz of Antares Pharma, Inc.; Kevin Warner of Winston & Strawn LLP; John C. Phillips, Megan C. Haney of Phillips Goldman & Spence P.A.

Dated: July 25, 2014

Respectfully submitted,

/s/ Imron T. Aly
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TABLE OF CONTENTS

Information Under Protective Order

The material omitted on pages 16 and 28 concerns information designated as “Confidential Information” by Defendants under the district court’s protective order. In particular, the information relates to testimony offered by Defendants’ expert in a transcript designated Confidential by Defendants.

TABLE OF AUTHORITIES

Cases **Page**

Statutes

STATEMENT OF RELATED CASES

This is the first time this case has been before this Court. It has not previously been before any other appellate court. Counsel for Antares are unaware of any other cases that would directly affect or be directly affected by the Court's decision in this appeal.

JURISDICTIONAL STATEMENT

The district court has jurisdiction under 28 U.S.C. §§ 1331 and 1338. This appeal is from the district court's July 10, 2014 denial of Antares's request for a preliminary injunction. A18. This Court has appellate jurisdiction over the refusal of the preliminary injunction under 28 U.S.C. §§ 1292(a) and 1292(c)(1) because this is a patent action arising under 35 U.S.C. § 251. Antares filed a timely notice of appeal. A944–45.

STATEMENT OF THE ISSUE

Did the District Court err in applying the "recapture rule" under 35 U.S.C. § 251 to limit the term "injection device" in a reissued patent to a "jet injector"—thereby denying a preliminary injunction—when the reissue claims cover a different invention encompassing the "overlooked aspect" of safety features in the original patent disclosure?

INTRODUCTION

This expedited appeal raises a straightforward legal issue concerning the application of 35 U.S.C. § 251. While straightforward, the issue is crucial to Antares, for it is currently the only seller of FDA-approved devices for administering methotrexate subcutaneously (under the skin) to treat rheumatoid arthritis and psoriasis. A16. Medac, however, plans to launch a competing device very soon, threatening immediate price erosion and irreparably diminishing Antares's brand. A16–17. Antares sought a preliminary injunction to bar Medac from selling a competing product that Antares alleges infringes its patents. A363; A382. While the court agreed with Antares that it was likely to suffer irreparable harm, the court denied the injunction on the ground that Antares was unlikely to succeed on the merits. A15–16. This erroneous holding was based squarely on a pure question of law: the applicability and application of § 251 and the recapture rule. Correcting this legal error is critical to Antares given the district court's finding that the company would otherwise suffer irreparable harm.

More specifically, the court applied the three-prong recapture test without first evaluating whether the Antares reissued patent claims cover a different invention from that originally claimed, thus falling entirely outside the "recapture rule." The recapture rule does not apply in this case because Antares claimed an automatic "jet" injector in its original patent and later claimed the "overlooked

aspects" of push-button safety features in its reissue patent. The original jet claims refer to performance criteria—pressure, speed, and time—because those features are important to ensure fast injections. The reissue claims, in contrast, do not refer to a jet injector but rather to safety features—needle guard, push button, and latch—features which are important to protect users of "injection devices" (whether jet or not) from accidentally sticking themselves with a needle. Where, as here, a reissue application is used to patent a separate invention, the recapture rule does not apply at all and the district court should have so found. *In re Youman*, 679 F.3d 1335, 1347 (Fed. Cir. 2012) ("Whereas the recapture rule applies when surrendered subject matter is being reclaimed, overlooked aspects by definition were never claimed and thus never surrendered."); *In re Mostafazadeh*, 643 F.3d 1353, 1360 (Fed. Cir. 2012) ("Because the subject matter of these claims was 'not originally claimed,' it is wholly unrelated to the subject matter that was surrendered during prosecution and the recapture rule is not even triggered.")

STATEMENT OF THE CASE

On January 27, 2014, Medac announced that it planned to launch a competing autoinjector product for the subcutaneous administration of methotrexate later this year. A189–90. On February 28, 2014, Antares sued Medac, contending that Medac's device infringed two Antares patents. A117–26, ¶¶ 57–124. Two weeks later, on March 14, Antares moved for a preliminary

injunction to block Medac's sale of the allegedly infringing product pending a final judgment on the merits. A192. Antares amended its complaint on April 18, 2014, adding two newly issued patents, including U.S. Patent No. RE 44,846, which is at issue in this appeal, A194–225, and simultaneously filed an amended motion for preliminary injunction asserting, *inter alia*, that Medac's device infringed claims 31, 34, 35, and 37 of the '846 patent. A363; A382.

The district court held a hearing on the preliminary injunction motion on June 26, 2014 and denied the request on July 10, 2014. A18. Applying the traditional preliminary injunction factors, the court agreed that "Antares has carried its burden of demonstrating irreparable harm," because Medac's entry into the market would cause Antares to suffer "the types of harm that traditionally have qualified as not easily compensable by money damages—price erosion and threatening its brand." A16. The district court also found that the balance of hardships and public interest factors were neutral. A17.

The district court denied injunctive relief, however, on the ground that Antares had not shown that it was likely to succeed on the merits. Specifically concerning the '846 patent, the district court held that under 35 U.S.C. § 251 and the "recapture rule," the claim term "injection device" meant "jet injector." The court concluded that "Antares has not carried its burden of showing likelihood of success on the merits that Medac's product infringes claims directed to a 'jet

injector.'" A13–16. This was the only reason expressed by the district court for denying Antares's motion with respect to the '846 patent. A15–16.

On July 21, 2014 Antares filed an agreed motion with this Court to expedite the appellate briefing schedule, which was granted on July 22, 2014. Antares has appealed the district court's denial of preliminary injunctive relief.

STATEMENT OF FACTS

Plaintiff-Appellant "Antares is a small, publicly traded, U.S.-based developer of automatic injection devices used to self-administer pharmaceuticals." A3. Antares began selling Otrexup™ in February 2014, which was the "first and only product approved by the FDA to administer methotrexate subcutaneously (under the skin) to treat rheumatoid arthritis (RA) and psoriasis." *Id*. In the fall of 2013, Defendant Medac Pharma "submitted a 505(b)(2) application with the FDA for a methotrexate injection product," making it a directly competing product to Antares's product. *Id*. Medac's proposed product will infringe several Antares patents, though this appeal focuses on one—RE 44,846 ("the '846 patent").[1] The '846 patent "is a reissue of U.S. Patent No. 7,776,015 ("the '015 patent")." A7. Antares asserted claims 31, 34, 35, and 37 of the '846 patent. A382.

[1] Given the expedited nature of this appeal, Antares is narrowly focusing its appeal to the '846 patent and the recapture issue. As the litigation proceeds beyond the preliminary injunction phase, the parties will revisit other issues regarding this and the other asserted patents, including the construction of the term "needle assisted jet injector" for the '631 patent considered below.

A. The Inventions Disclosed in the Specification

The ‘015 patent issued on August 17, 2010. A7; A32. The ‘015 patent prosecution history included discussion about the “jet” aspect of the disclosed inventions. A8–10; A13–14. The ‘846 patent application was filed on June 22, 2012, within two years of the issuance of the ‘015 patent. A10; A70. The ‘846 patent prosecution focused exclusively on previously overlooked features, instead of the “jet” aspect of the original claims.

There are multiple inventions disclosed in the shared specification of the ‘015 and ‘846 patents. Antares first obtained “jet” invention claims in the original ‘015 patent (A66–67 at 14:1–16:34) and then, by reissue, kept all of those claims and added separate claims in the ‘846 reissue patent directed to safety features for “injection devices.” A104–106 at 13:65–18:24. The original “jet” claims focus on performance—pressure, speed, time, *see, e.g.,* A104 at 14:16–18; 14:38–66—whereas the reissued claims address safety features that are very different and focus on needle stick prevention—a pushbutton on the top of a device that releases a latch, a moving needle cover, and unlocking the pushbutton only when the needle cover is pushed back during operation. *See, e.g.*, A106 at 17:6–23; 18:18–23. There is no limitation in claim 31 of the ‘846 reissue patent requiring a jet injector and no structure limited to a jet injector. A105-106 at 16:56-18:2.

The ‘015 and ‘846 patents share the same specification. A32–67; A70–106. The shared specification describes solutions to multiple problems in the prior art, and therefore multiple inventions. One problem concerns prior art jet injectors that do not use needles, requiring very large delivery pressures “typically greater than approximately 4000 p.s.i.” in order to penetrate tissue. A98 at 1:43:44. These needle-free “jet” injectors already existed, as the patent acknowledged, but Antares invented a “*needle assisted* jet injector that operates at relatively low pressure and that is capable of quickly delivering medicament.” A98 at 2:45–47 (emphasis added).

One invention recited in claim 1 of the ‘015 and ‘846 patents, is therefore a needle assisted “jet” injector with associated performance criteria like pressure, rate, and time. A98 at 2:45–47. These jet injectors did not use the very high “4000 p.s.i.” pressures of prior jet injectors, and with the added needle obtained the benefit that “lower peak pressure can be used to deliver the medicament to the desired region and still achieve a short injection time.” A103 at 12:58–60. This benefit is important because “[r]educed operating pressure decreases the chances of glass ampule breakage,” *id.* at 12:63–64, which “typically cannot withstand the pressure typically reached by [prior art] jet injectors.” A98 at 1:63–64. And “[a]nother advantage . . . is the decreased injection time compared to syringes or autoinjectors.” A104 at 13:28–29.

In describing another invention, the ‘846 patent discloses safety features that are separately patentable—for any needle-assisted auto-injector, whether jet or not. In particular, Antares disclosed a series of safety features, several of which are summarized in this paragraph:

> The device of the preferred embodiment is operated by first turning ***the safety cap*** 800 clockwise one quarter of a turn, to create the drug path by inserting the proximal end of injecting needle 480 into the ampule 320. Rotating the safety cap 800 also aligns the cutaways 645 in the safety cap 560 with the bosses 625 on the inner housing 25, allowing the needle guard 540 to be depressed. Next the safety cap 800 and consequently the needle cap 820 are removed from the device. As the distal end of the device is pressed against the injection site, ***the needle guard*** 540 moves longitudinally toward the proximal end of the device and the injecting needle 480 enters the skin to a depth of between 1 and 5 mm. The movement of the needle guard 540 causes the ram 125 to fire and consequently between 0.02 and 2.0 ml of medicament 400 is forced out of the ampule 320 and through the drug path in under about 2.75 seconds. Once the device is removed from the injection site, the needle guard 540 returns to its original position under the force of return spring 660, concealing the injecting needle 480. The ***locking ring*** 700 locks the needle guard 540 in place to prevent re-exposure of the injecting needle 480. Alternatively, a ***push button*** could be located at the proximal end of the device and be locked in an idle position. The movement of the needle guard 540 could ***unlock the push button*** and allow the user to depress it and consequently fire the device.

A103 at 11:57–12:14 (emphasis added).

The patent therefore disclosed a different embodiment with a “safety cap,” a “needle guard” with multiple positions including a “lock[ed]” position, and a “pushbutton” on the top of the device that is unlocked by the needle guard. A103 at 11:57–12:14 This passage does not use the word “jet,” and although it is

understood that these features ***can*** be used with jet injectors, there is no requirement that they ***must*** be used with jet injectors. *Id*. The safety features apply to any needle-based automated injector.

When later claiming the safety features, Antares used the broader term "injection device" precisely because the safety features relate to a separate aspect of the inventions in the specification, and apply to any injection device. *E.g.*, A105–06 at 16:59–18:2. As the specification describes, a "push button could be located at the proximal end of the device and be locked in an idle position," and moving the needle guard "could unlock the push button and allow the user to depress it and consequently fire the device." A103 at 12:11–14. Unlike the "jet" injector claims, with the pressure requirements and potential glass breakage, such concerns are entirely irrelevant to the safety features invention: covering the needle with a guard, having a pushbutton on the top of the device, and locking the pushbutton until it is ready for use. A103 at 12:11-14; A106 at 17:6-23. For any auto-injector, these features help "prevent[] re-exposure of the injecting needle." A103 at 11:40–41.

B. The Prosecution of the '015 and '846 Patents

All claims of the '015 patent include the word "jet" in the preamble. A66–67 at 14:1–16:34. A "jet" injector as used in the '015 patent refers to a high-performance injector: "a particular class of injector that injects medicament by

creating a high-speed jet of the medicament that penetrates the tissue of the patient to a distance beyond the exit of the injector." A62 at 6:22–26. This explains the relevance of pressure and delivery time, terms that the patent specification associated with jet injectors. A65 at12:35–62. Claim 1 of the '015 patent reflected the jet invention and claimed performance-based criteria, such as "a fluid pressure of about between 100 and 1000 p.s.i. to penetrate patient tissue to a distance through and axially beyond the insertion point to an injection site." A66 at 14:20–23.

The prosecution of the '846 reissue patent, however, was different. All of the originally issued claims remained intact in the reissue, as is, including the "jet" term. *See* A591–94. The added claims—including asserted independent claim 31—did not require any performance criteria or any other characteristics of a jet. Instead, these were claims to safety features, which could be used with any type of injection device, whether or not a jet injector. The preamble to the new claims in the '846 patent therefore all referred to the umbrella term "injection device." A105–06 at 16:4–18:24.

The prosecution histories for the two patents support two patentably distinct inventions. During prosecution of the '015 patent, the Patent Office rejected the pending "jet" claims "under 35 U.S.C. § 102(b) over Kramer." A652. Because the claims of the '015 patent were directed to jet injectors, Antares argued that

"Kramer, however, does not define a jet injection device." *Id*. Antares did not add the term "jet" by amendment, and simply explained that its jet invention was different than the prior art. *See* A648–51 (identifying "original" claims).

If, as the district court found, the new reissue claims were intended to cover a "jet" injector, they could have been distinguished over Kramer for the same reasons used during prosecution of the '015 patent. But that is not what happened. During the prosecution of the '846 patent, the Patent Office rejected the pending safety features claims "as anticipated by Kramer et al.," the same prior art reference evaluated during the '015 patent. A600. Because the new reissue claims were addressed to a different invention, Antares did not add or argue—and did not need to add or argue—a "jet" limitation to overcome the rejection. Instead, Antares pointed out that Kramer lacked "a latch and a spring located within the proximal end of the injecting device" and further lacked a series of related safety features including "a pushbutton . . . in activating communication with the latch," "movement of the needle guard . . . unlocks the pushbutton," and "depressing the pushbutton to activate the latch and release the spring." A602. The Patent Office agreed and reissued the patent. A68.

C. The Claims of the '015 and '846 Patents Are Directed to Different Inventions

Antares obtained two different sets of claims, the original '015 claims for the jet invention and the '846 reissue claims for the safety features. The following

shows original claim 1 (found both in the ‘015 patent and the reissued ‘846 patent) and the newly added claim 31 of the ‘846 patent:

> **1. A jet injection device, comprising:**
>
> a housing member having distal and proximal ends;
>
> a fluid chamber within the housing member holding about between 0.02 ml and 3 ml of a medicament comprising fluid;
>
> an injection-assisting needle disposed at the distal end of the housing member, having an injecting end, and having an association with the fluid chamber to provide a fluid pathway from the fluid chamber through the needle, the injecting end of the injection-assisting needle having an axial opening for ejection of the medicament;
>
> a plunger movable within the fluid chamber; and
>
> a force generating mechanical member within the housing member that is elastically-deformed so as to provide sufficient force to eject the medicament from the fluid chamber through the needle by jet injection in a high-speed jet that exits the injecting end of the needle through the axial opening thereof at a fluid pressure of about between 100 and 1000 p.s.i. to penetrate patient tissue to a distance through and axially beyond the insertion point to an injection site;
>
> wherein the injecting end of the needle has a position extending from the housing member by a length selected for inserting into a patient such that the injecting end reaches a needle insertion point at a depth of up to about 5 mm below the surface of the patient's skin; and
>
> wherein the device is further configured such that activation of the force generating mechanical member applies the generated force to the plunger to expel the medicament from the fluid chamber. (A104 at 13:66–14:30.)
>
> **31. An injection device comprising:**
>
> an outer housing member having distal and proximal ends;

> an inner housing member located within the outer housing member;
>
> a cartridge assembly disposed within the housing member, the cartridge assembly comprising a medicament;
>
> a plunger movable within the cartridge assembly;
>
> a needle assembly in fluid communication with the cartridge assembly and comprising an injecting needle;
>
> a spring within the proximal end of the outer housing member in force communication with a ram which is in force communication with the plunger to expel medicament from the cartridge assembly through the injecting needle;
>
> a latch within the proximal end of the outer housing member and in releasing communication with the spring;
>
> a pushbutton located at the proximal end of the outer housing member and in activating communication with the latch;
>
> a needle guard in communication with the pushbutton, at least a portion of the needle guard is located within the distal end of the outer housing member, the needle guard having an orifice through which the injecting needle passes, and wherein the needle guard has an extended sliding position, a retracted position when the medicament is expelled from the cartridge assembly and an extended locked position after the medicament is expelled from the cartridge assembly; and
>
> wherein movement of the needle guard communicates with and unlocks the pushbutton to permit a user to manually fire the injection device by depressing the pushbutton to activate the latch and release the spring; and
>
> wherein before the needle guard moves from the extended sliding position toward the retracted position, the spring is under a compression sufficient to provide a force to expel the medicament from the cartridge assembly. (A105–06 at 16:59–18:2.)

These are two different inventions, and not just because they are two different claims. Claim 1 is a claim directed to "jet injection device" ***performance***,

with a "fluid pressure of about between 100 and 1000 p.s.i. to penetrate patient tissue." A104 at 13:66 and 14:18-20. It also includes limitations regarding volume ("between 0.02 ml and 3 ml"), needle length ("about 5 mm below the surface"), and drug deposition ("beyond the insertion point to an injection site"). A104 at 14:2-3, 14:20-26. Claim 31, on the other hand, is directed to ***safety features*** for any "injection device." A105-106, at 16:59-18:2. Claim 31 includes a "latch," a "pushbutton" on the top of the device to release the latch, and a "needle guard" that "unlocks the pushbutton"—all safety features for automated injection devices generally. A105–06 at 16:59–18:2. It is not as if one or two limitations were modified; rather, the entire claim scope is different because these are two different inventions.

Both "injection device" and "jet" are supported by the specification, and a jet is a type of injection device. In the "Field of Invention," the '846 patent states that "[t]he present invention is directed to a device for delivery of medicament, and in particular to a jet injector with a short needle to reduce the pressure at which the jet injector must eject the medicament for proper delivery." (A98 at 1:24–27.) The specification is thus directed generally to injection devices, and the patent uses jet injectors to exemplify different aspects of the invention.

The safety features claimed in claim 31 of the '846 patent do not require the use of a jet injector. They could be used with any needle-based auto injector. This

is not disputed. [redacted]

SUMMARY OF THE ARGUMENT

Section 251 permits a patentee to obtain reissued patents with a modified claim scope or to claim different inventions. 35 U.S.C. §§ 251(a), (d). Where a patentee seeks to enlarge claim scope within two years of the grant of the original patent by way of reissue, the "recapture rule" prevents taking back claim scope that was surrendered during prosecution of the original patent. Where a patentee seeks to claim different inventions—overlooked aspects—from the original specification by way of reissue, the recapture rule does not apply at all. *In re Youman*, 679 F.3d 1335, 1347 (Fed. Cir. 2012); *In re Mostafazadeh*, 643 F.3d 1353, 1360 (Fed. Cir. 2011). This is an issue of first impression because, while this Court has repeatedly stated that "overlooked aspects of the disclosed invention" can be claimed in

reissue without the "need to apply the recapture rule in the first place," this Court has not had the opportunity to actually apply this principle. *Mostafazadeh*, 643 F.3d at 1360.

Claim 31 of the '846 reissue patent appropriately uses the term "injection device," because the claim refers to a series of safety features that can be used with any needle-based autoinjector. A different "jet" invention was claimed in the original '015 patent, and the original claims are therefore limited to a "jet injection device." It is not, however, a violation of § 251 to claim a separate "overlooked aspect" of an invention in a reissue, and it was error for the district court to apply the "recapture rule" without considering the overlooked aspects doctrine.

Once the district court's legal error is recognized, it follows that the district court also erred in concluding that Antares failed to carry its burden to show likelihood of success on the merits as to the '846 patent and in denying Antares's motion for a preliminary injunction. The decision should be reversed.

STANDARD OF REVIEW

The denial of a preliminary injunction is reviewed under the abuse of discretion standard, but "when a preliminary injunction is denied because of an error of law . . . the legal issue is reviewed *de novo*." *Globetrotter Software, Inc. v. Elan Computer Group, Inc.*, 236 F.3d 1363, 1367 (Fed. Cir. 2001). "Determining whether the claims of a reissued patent violate 35 U.S.C. § 251 is a question of

law, which [this Court] review[s] de novo." *Medtronic, Inc. v. Guidant Corp.*, 465 F.3d 1360, 1373 (Fed. Cir. 2006).

ARGUMENT

Section 251(a) of the Patent Act allows patentees to seek reissued patents "by reason of the patentee claiming more or less than he had a right to claim in the patent." 35 U.S.C. § 251(a). Section 251(d) allows patentees to seek claims "enlarging the scope of the claims of the original patent" so long as a reissue application is filed "within two years from the grant of the original patent." *Id.* § 251(d). The reissue statute is to be construed liberally. *See In re Weiler*, 790 F.2d 1576, 1579 (Fed. Cir. 1986). A broadening reissue is limited by the so-called "recapture rule," which prevents an applicant from "regaining through reissue the subject matter that he surrendered in an effort to obtain allowance of the original claims." *In re Clement*, 131 F.3d 1464, 1468 (Fed. Cir. 1997).

I. The Recapture Rule of 35 U.S.C. § 251 Does Not Apply

Antares obtained the '015 patent and then relied upon § 251 to obtain claims covering previously overlooked aspects. The reissue claims accordingly recite safety features that can be used not only with the jet injectors claimed in the original patent, but also with *any* auto-injectors. To make that clear, Antares used the "injection device" claim term when describing the safety features claimed in the '846 patent. No physical requirement limits the operation of the safety features

in the ‘846 patent to only a “*jet* injection device.” Nonetheless, the district court ruled that even the safety features had to be limited to a “jet injector.” A15–16. It did so based on an erroneous application of 35 U.S.C. § 251 and the “recapture rule.” A13–15.

Medac opposed Antares’s request for injunctive relief by asserting the recapture rule argument; Medac accordingly had the burden to show that an improper recapture had occurred, even at the preliminary injunction stage. “[F]or preliminary injunction purposes . . . ‘[a] patent shall be presumed valid. . . . The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.’” *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1346 (Fed. Cir. 2008) (quoting 35 U.S.C. § 282).

A. The recapture rule prevents claiming surrendered claim scope in a reissue patent for the same invention claimed in the original patent.

The basis for the recapture rule is plain: a patentee should be estopped from eliminating from an existing claim the very element that was used to obtain the claim. *Hester Indus, Inc. v. Stein, Inc.*, 142 F.3d 1472, 1480 (Fed. Cir. 1998). The MPEP exemplifies impermissible recapture via the following example: a patentee originally claims “ABCD,” then amends during prosecution the claim to “ABCDE” arguing E is critical to patentability. A976 § V. Subsequently, the

patentee attempts through reissue to recapture only "ABCD" by itself. *Id*. That, of course, is an improper recapture.

The cases applying the recapture rule follow the same basic fact pattern as the MPEP example—they relate to the same invention, with one key claim term removed or slightly modified in reissue, but with everything else remaining substantially the same. In *Hester*, the original patent claim required a cooking system that cooked "solely with steam," while the reissue claim tried to cover anything that used "a source of steam," even if other energy sources were also used. 142 F.3d at 1477. Both were otherwise still claiming the same aspect of the invention, cooking food with steam, and the other claim terms remained substantially unchanged.

In *MBO Laboratories, Inc. v. Becton, Dickinson & Co.*, the original claim required a syringe with a needle that "moved toward the safety device," whereas the reissue claim modified that phrase to "any relative movement between the needle and the body." 602 F.3d 1306, 1311 (Fed. Cir. 2010). Here again, both claims covered the same exact syringe, deleting only the key element of the direction of movement. The claims were otherwise substantially the same.

In *Mostafazadeh*, the original claim required an integrated circuit package with a "circular portion formed as an attachment pad," and the reissue claim removed "circular" to read "a portion that forms an attachment pad." 643 F.3d

1356–57, n.2, n.3. Both were still claiming the same integrated circuit package, and not something different. The claims were otherwise the same. Indeed, the Patent Board had found that the reissue claims were "not directed to distinct inventions; rather they [were] different definitions of the same . . . embodiment." *Id*.

Importantly, the patentee in each of those cases did not claim, via reissue, a different invention from that originally claimed or obtained, so the recapture rule was properly applied. As explained herein, however, Antares's '846 patent does claim a different invention from the '015 patent encompassing overlooked aspects from the invention. This is a case where the recapture rule does not apply.

B. The recapture rule does not apply where a patentee seeks to claim an "overlooked aspect," i.e., a different invention, in a reissue patent.

The present facts are different, because the reissue claims here do not claim substantially the same invention. Antares used the reissue procedure to claim a different invention disclosed in the original specification, an invention that was never surrendered during prosecution of the '015 patent. As a threshold matter, the recapture rule does not apply in this circumstance, because the '846 patent fits squarely within a recognized exemption to the rule, known as the "overlooked aspects" doctrine. An overlooked aspect refers to "additional

inventions/embodiments/species not originally claimed." *Mostafazadeh*, 643 F.3d at 1360 (quoting MPEP).[2]

Mostafazadeh makes clear that the recapture rule is not triggered for "reissue claims directed at additional inventions/ embodiments/species not originally claimed." 643 F.3d at 1360. By its very nature, "[b]ecause the subject matter of these claims was 'not originally claimed,' it is wholly unrelated to the subject matter that was surrendered during prosecution and the recapture rule is not even triggered." *Id*. In this situation, "there is no need to apply the recapture rule in the first place." *Id*. That is why the "overlooked aspects" doctrine represents a *separate* question—whether the recapture rule applies at all—which the court must answer before turning to the commonly used three-step test for applying the recapture rule.[3] Here, the district court failed to address the question whether the recapture rule is even triggered.

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[2] The MPEP defines overlooked aspects as "patentably distinct (1) inventions; (2) embodiments; or (3) species not originally claimed—not mere incidental features of the originally-claimed invention." *Mostafazadeh*, 643 F.3d at 1360 (quoting MPEP); A968 (MPEP).

[3] "We apply the recapture rule as a three-step process: (1) first, we determine whether, and in what respect, the reissue claims are broader in scope than the original claims; (2) next, we determine whether the broader aspects of the reissue claims relate to subject matter surrendered in the original prosecution; and (3) finally, we determine whether the reissue claims were materially narrowed in other respects, so that the claims may not have been enlarged, and hence avoid the recapture rule." *N. Am. Container, Inc. v. Plastipak Packaging, Inc.*, 415 F.3d 1335, 1349 (Fed. Cir. 2005)

In *Youman*, this Court reiterated that the "overlooked aspects" doctrine is a "separate inquiry under reissue" as a threshold question to see if the recapture rule is triggered. 679 F.3d at 1347. This Court explained that the Patent Board again incorrectly asserted that the "overlooked aspects" doctrine was covered by the third step of the recapture rule analysis. The Board "incorrectly evaluated whether other limitations added during reissue materially narrow based on whether those added limitations were directed to an 'overlooked aspect' of the invention." 679 F.3d at 1347. Further, "[w]hereas the recapture rule applies when surrendered subject matter is being reclaimed, overlooked aspects by definition were never claimed and thus never surrendered." *Id*.

Similarly, the MPEP explains that the recapture rule does not apply when the reissue patent claims a different invention compared to the original patent: "the focus in the analysis of the second step must be on the subject matter that was surrendered during the original application prosecution in the context of the then-existing claims, ***not separate inventions/embodiments/species, which do not even trigger a recapture analysis***." A968 (emphasis added). Where separate inventions are claimed, a recapture analysis is not triggered.

The MPEP provides examples where the recapture rule does not apply. In the MPEP example, an original claim was directed to a "method of making a glass lens," with amendments made during prosecution towards a specific technique

involving "molten bath ion implantation" and distinguished over the prior art based on pressure and temperature limitations. *Id.* Reissued claims to even a slightly different embodiment—unrelated to the amendment—would not invoke the recapture rule, such as "using a plasma stream rather than a molten bath to provide the ions." A969. The MPEP provides a second example of a different invention, where the reissued claims are directed to ways of configuring glass lenses, such as by "placing two lenses made by the invention in a specified series," regardless of how the lenses are made. *Id.* In each of these examples, the MPEP notes that reissued claims involving different inventions are "proper 35 U.S.C. 251 error, which can be corrected by reissue." *Id.* Any surrendered claim scope during prosecution of the original invention, such as pressure or temperature, would be "totally irrelevant" to either of the two examples. *Id.*

In the *Mostafazadeh* case, the Patent Board assumed that "overlooked aspects" was something to consider as part of the third step of the recapture rule analysis, whether the reissue claims had been "materially narrowed."[4] 643 F.3d at 1360. This Court in *Mostafazadeh* made clear that "overlooked aspects" puts a reissue outside the recapture rule: a patentee can claim a different invention, independent of the recapture rule, regardless of whether there was a "materially

[4] The Board noted that "[a] limitation materially narrows the . . . claims if the narrowing limitation is directed to one or more overlooked aspects of the invention." *Id.*

narrowed" claim. But as this Court stated in correcting the Patent Board, the overlooked aspects exception applies to "claims in which ***there is no need to apply the recapture rule in the first place***," *Mostafazadeh*, 643 F.3d at 1360 (emphasis added), because "the reissue claim(s) are really claiming additional inventions/embodiments/species not originally claimed (i.e. overlooked aspects of the disclosed invention)." *Id*. at 1360 (quoting MPEP). There is an "either-or" approach: either there are overlooked aspects, in which case the recapture rule does not apply, or there are no overlooked aspects, in which case the three steps of the recapture rule are applied.

The CCPA similarly recognized years ago that "as for obtaining claims on reissue which are different, no prohibition arises merely because of the language of the reissue statute." *In re Wadlinger*, 496 F.2d 1200, 1207 (C.C.P.A. 1974) (Rich, J.). Accordingly, the MPEP, *Mostafazadeh*, *Youman*, and this Court's precedent from the CCPA all make clear that if the claims in the reissue encompass a different invention or embodiment not claimed in the original patent, the recapture rule does not apply.

C. The '846 patent claims an "overlooked aspect" directed to a different invention but the district court erroneously failed to consider this issue.

In this case, the district court made the same mistake that the Patent Board did in *Mostafazadeh* and *Youman*. It assumed that the "overlooked aspects"

question was the same as the "materially narrowed" part of the recapture rule test. A12. That is, respectfully, error given this Court's precedent allowing a patentee to avoid the recapture rule entirely where reissue claims are directed to a different invention compared to the original patent.

The district court never considered the "overlooked aspects" inquiry to determine whether the recapture rule was even triggered. Rather than separately consider whether the claims of the '846 patent encompassed a different invention from the claims of the '015 patent, the court simply applied the three-pronged recapture test. A12–13. Moreover, the court pointed to arguments made during prosecution of the '015 patent to support the proposition that Antares surrendered scope regarding a "jet" invention, without considering the fact that the '846 patent is directed to a different invention. A13–14. The district court accordingly applied the three-prong test without clearing the threshold gate of considering the overlooked aspects doctrine. A13–15.

The district court's error appears to stem from relying upon the *Hester* decision, without considering the instructions in *Mostafazadeh* and *Youman*. A12–13. In discussing the third prong of the recapture rule test, the district court quoted *Hester*, stating that the "recapture rule can be avoided only if the reissue claims 'are materially narrower in other overlooked aspects of the invention.'" A12, quoting *Hester*, 142 F.3d at 1482-83. This was, however, the very same mistake

made by the Patent Board and corrected by this Court in *Mostafazadeh* and *Youman*. The "overlooked aspects" doctrine is not part and parcel of the "material narrowing step" of the recapture rule, and it is not accurate to conflate the two. They are fundamentally distinct: if the "overlooked aspects" doctrine applies, the recapture rule does not, and there is no need to evaluate the reissued claims under the three prong test.

1. The asserted '846 reissue claims cover a different invention than what was claimed in the '015 patent.

Antares kept all of the 22 claims intact from the original '015 patent, without changing or removing any limitations. A104–05 at 13:66–16:3. Those original claims had performance criteria limitations, like pressure (claim 1 requires "fluid pressure of about between 100 and 1000 p.s.i."), A104 at 14:12–19, speed (claim 5 requires "a rate of at least 0.40 ml/sec"), *id.* at 14:38–41, and time (claim 6 requires injection "in less than about 2.75 seconds"). *Id.* at 14:42–45. Moreover, as pointed out in the district court's decision, A8–10, Antares first claimed the "jet" invention in the '015 patent, and explained why the jet was different than the prior art. Antares's arguments, however, did not surrender any of the safety features later claimed in the '846 reissue patent.

The new claims of the '846 reissue were *not* used to recapture surrendered subject matter, by trying to get claims that were the same as the original claims without the word "jet," but rather to claim ***different*** subject matter, specifically the

various safety features. And that in turn is why the new claims of the '846 patent, including claim 31, use the general term "injection device." The reissue claims do not have any performance criteria like pressure, rate, or time, as the original claims did. *See* A105–06 at 16:4–18:23. Instead, they focus on safety features like a "needle guard" that is used to unlock a "pushbutton" on the top of a device (claim 31 requires "movement of the needle guard communicates with and unlocks the pushbutton"), A106 at 17:20–23, a see-through housing to check for medicament levels (claim 34 requires "transparent material"), *id.* at 18:9–11, and a "safety cap" (claim 37). *Id.* at 18:21–23. These were overlooked aspects of the original patent that did not require a "jet" and that one of ordinary skill in the art would know could be used with any type of auto-injector.

[redacted]

The specification also supports the difference between jet injector performance criteria and safety features. The district court noted that "the specification and the claims mention 'jet injection,' 'jet injector,' and like phrases over 75 times." A14, n.8. The section from column 10, line 43, to column 12, line 14 (A102-103) describes how the needle cover of the '846 patent imparts needle safety, including the claimed functionality that "[t]he movement of the needle guard 540 could unlock the push button and allow the user to depress it and consequently fire the device." A103 at 12:12–14. These are not limited to a jet, and there is no disclaimer suggesting the features must be used with a jet. The safety features are a distinct invention, and Antares properly used section 251 to cover this subject matter.

Under a proper application of the "overlooked aspects" doctrine, the new claims in the '846 reissue patent refer to a separate invention, so the recapture rule is never triggered and should not have been considered. The asserted '846 reissue claims are directed at "additional inventions/embodiments/species not originally claimed" so "it is wholly unrelated to the subject matter that was surrendered during prosecution and the recapture rule is not even triggered." *Mostafazadeh*, 643 F.3d at 1360. Claim 31 of the '846 patent does not improperly recapture subject matter that was surrendered during the prosecution of the original '015 patent.

This case is analogous to the MPEP discussion above, which explained how different inventions can be separately claimed by reissue, without limiting them to amendments made during the original patent prosecution. *See* A968–69. In the MPEP example, original claims were to a "molten bath" technique, and the patentee amended them during prosecution to add temperature and pressure limitations. *Id.* Corresponding to the "molten bath" example, Antares first claimed a jet invention. The reissue claims in the MPEP example related to two inventions different from a molten bath: a "plasma stream" technique and "placing two lenses" in a particular configuration. *Id.* These examples were not directed to a "molten bath" technique, so the recapture rule did not apply. So too here, the new '846 reissue claims can be used with any injection device, not just "jet" injectors, so the recapture rule does not apply. The safety features are a distinct invention that addresses the problems of needle sticks and accidental injections, which are not addressed in claim 1. The earlier prosecution history arguments are "totally irrelevant." *Id.*

2. The prosecution history confirms that the reissue claims cover "overlooked aspects"

The prosecution history of the '846 patent also confirms that there are two different inventions. This is clear because it was the same prior art—the Kramer '643 reference—that was distinguished both during prosecution of the original '015 patent and during prosecution of the '846 reissue. But they were

distinguished in different ways for each separate invention. Antares distinguished the '015 original patent claims over Kramer in view of the "jet" limitation. *E.g.*, A558–63; A572–78; A652–56; A665–69. Antares distinguished the '846 reissue claims over Kramer by pointing out that Kramer did not have any of the several safety features, let alone the combination, that Antares was pursuing in the reissue application. A599–602. Antares noted that Kramer lacked a latch and spring located "within the proximal end of an injecting device," a "pushbutton located at the proximal end . . . in activating communication with the latch," "movement of the needle guard . . . unlocks the pushbutton," and "depressing the pushbutton to activate the latch and release the spring." A600–02. Claim 31 includes all of these safety features, which need not be limited to a jet injector. A105–06 at 16:59–18:2.

To fit within the recapture rule cases, Antares would have had to claim substantially the same subject matter in the reissue as it did in the original patent. *See Mostafazadeh*, 643 F.3d at 1360 (affirming recapture rejection where reissued claims "were not directed to distinct inventions [but] rather they were different definitions of the same . . . embodiment"). For example, there *could* have been a recapture concern if Antares had sought pressure, rate, or speed claim terms—these relate to performance criteria—without using the word "jet." But that is not what happened.

Put more generally, the claimed combination of push button safety features are "add-on" features. The "add-on" features do not have to be used with jet injectors. The safety features of the new, reissued claims can be used with any "injection device" that meets the other claim limitations. By way of analogy, a patent specification might describe a race car with an "add-on" feature of intermittent windshield wipers. The wipers, like the safety features of the '846 patent, may be separately claimed without requiring a race car. Even though the wipers might be shown in the specification on a race car, that would merely exemplify the safety features *in the context of* a race car, but it would not require that claims to wipers must *always be limited to* a race car. This is a simpler version of the MPEP example where the original claims refer to a "molten bath" process for making lenses, whereas a later reissue sought claims regarding "placing two lenses made by the invention in a specified series." A968–69. Thus, even though the district court found that the features in claim 31 were "in the context of a jet injector," (A16), that is irrelevant because the safety features still reflect a separate invention. As these are two different inventions, with materially different scope, it was a "proper 35 U.S.C. 251 error, which can be corrected by reissue." A969.

3. Even under *Hester*, the '846 patent still relates to a separate invention and therefore avoids the recapture rule.

Alternatively, even if the Court were to use the standard as set forth in *Hester* and not as set forth in *Mostafazadeh* and *Youman*, the '846 patent still would meet the test in two ways. First, the "overlooked aspects" issue should still be treated as a separate question, even if it were addressed within the context of the recapture rule. The analysis in *Hester* still requires determining whether the reissue claims refer to a separate invention, because a patentee may claim "a scope of protection to which he is rightfully entitled for such overlooked aspects." *Id*. at 1483. Second, unlike *Mostafazadeh* and *Youman*—which consider material narrowing only if the claims are "materially narrowed relative to the surrendered subject matter," *Mostafazadeh*, 643 F.3d at 1361; *Youman*, 679 F.3d at 1347—*Hester* considers "whether the reissue claims were materially narrowed ***in other respects***," not limited only to the surrendered subject matter. *Hester*, 142 F.3d at 1482-83 (emphasis added).

As discussed above, the added safety features in claim 31 of the '846 patent represent materially narrowed terms as compared to claim 1 of the '015 patent, as evidenced by the claim scope and prosecution history for the two patents. Claim 31 adds substantial limitations, including the push button, latch, needle guard unlocking feature, and needle guard locking features, none of which are present in claim 1. These terms materially narrow the scope of claim 1 because even jet

injectors claimed in claim 1 would not infringe if they did not have one or more of these claimed safety features and the interaction between them. Moreover, during prosecution, the Patent Office found claim 31 to be patentable over the Kramer '643 reference—the same reference considered during the original prosecution for claim 1—without using the "jet" distinction. This also shows that the additional limitations in claim 31 materially narrow the scope of the claim, because they uniquely distinguished the Kramer reference. Unlike in *Hester*, where the reissued claims "were included in original claim 1," the safety limitations of claim 31 refer to features not originally claimed. *Hester*, 142 F.3d at 1483.

D. The recapture rule does not apply in this case, and the district court's decision to the contrary was in error.

Accordingly, this is not a case where the "recapture rule" applies in the first place—and the district court's failure to even consider this threshold issue was legal error. That error was compounded here because, there *were* in fact overlooked aspects, as there were additional independent inventions claimed in the '846 reissue patent apart from the "jet" invention claimed in the original '015 patent. Had the district court proceeded correctly, it would not have engaged in its erroneous recapture rule analysis, and therefore would not have reached its erroneous conclusion that "Antares has not carried its burden of showing likelihood of success on the merits." A16.

II. The Court Erred In Finding Medac Did Not Infringe the '846 Patent

A. Medac's accused product is an "injection device."

Because the overlooked aspects exemption applies in this case, claim 31 and the other asserted claims avoid § 251's recapture rule entirely. Nonetheless, the district court used § 251 to conduct its non-infringement analysis:

> To allow the patentees to remove this [jet] limitation and claim features that were only described in the context of a jet injector does not fit within the realm of corrections contemplated within ***§ 251***. As discussed above in the analysis of the '631 patent, Antares has not carried its burden of showing likelihood of success on the merits that Medac's product ***infringes*** claims directed to a "jet injector."

A16 (emphasis added). Without the "jet" requirement, Medac's device clearly meets the "injection device" term in claim 31. Medac does not and cannot dispute this fact. It has an injection device. Applying the proper claim term, Antares is likely to succeed on its claim.

B. Alternatively, even if the "injection device" of the '846 patent is limited to a "jet injector," Medac's product still infringes.

In the alternative, even if the term "injection device" were limited to a "jet injector," it was still improper for the district court to use the same definition of "jet injector" that it used for the '631 patent. The district court's infringement discussion for the '846 patent, as quoted above, refers to the "analysis of the '631 patent." A16. The court also provided an alternative approach to reach the same conclusion construing "injection device" to be "consistent with its construction of 'jet injector' in the '631 patent." A15, n.10. But the '846 patent expressly defines

"jet injector," and it is not consistent with the definition the court used for the '631 patent. In the '846 patent, "the term jet injection means a particular class of injector that injects medicament by creating a high-speed jet of the medicament that ***penetrates the tissue of the patient to a distance beyond the exit of the injector***." A100 at 6:22–26 (emphasis added). This definition was reiterated during prosecution. A572. That is the proper construction for a "jet injector."

Even assuming that reissue claim 31 is deemed to be limited to a "jet injector," Medac's product still infringes under the correct construction of "jet injector" in the '846 patent. For the '631 patent, the district court found in its preliminary construction that a "jet" required medicament to be "dispersed" and not a "bolus," A5, and used these same terms when conducting its infringement analysis. A7. But Antares showed that Medac's device "penetrates to a deeper portion of the block . . . in contrast to the lack of jet." A5. And Becton-Dickinson, the manufacturer of Medac's device, did testing "showing that drug was deposited over 17.5 mm beneath the skin with the autoinjector, something a manual injector could not do."[5] A6 (internal quotation omitted). Evidence Antares presented for the '631 patent showed deeper penetration is possible with Medac's device

[5] For the Becton clinical testing report, the district court also referred to testimony that the 17.5 mm data point was an "'outlier,' labeled 'statistically outlying values.'" A6. Even one instance of infringement is still infringement, and the tests show that Medac's proposed product is capable of infringing. *See, e.g.*, *Organic Seed Growers & Trade Ass'n v. Monsanto Co.*, 718 F.3d 1350, 1356 (Fed. Cir. 2013) (discussing how even "trace amounts" infringe).

compared to a conventional syringe. A836-838, ¶¶ 15–22. These facts prove that Medac's device meets the express definition of "jet" in the '846 patent, which requires penetration, and not the separate dispersion and non-bolus qualifiers that the district court added for its preliminary construction of the "jet injector" claim term. *See* A5.

CONCLUSION

The district court's order should be reversed, and the case remanded with the instruction for the entry of a preliminary injunction.

Respectfully submitted,

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STATUTORY ADDENDUM

35 U.S.C. § 251

(a) In General.— Whenever any patent is, through error, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue.

(b) Multiple Reissued Patents.— The Director may issue several reissued patents for distinct and separate parts of the thing patented, upon demand of the applicant, and upon payment of the required fee for a reissue for each of such reissued patents.

(c) Applicability of This Title.— The provisions of this title relating to applications for patent shall be applicable to applications for reissue of a patent, except that application for reissue may be made and sworn to by the assignee of the entire interest if the application does not seek to enlarge the scope of the claims of the original patent or the application for the original patent was filed by the assignee of the entire interest.

(d) Reissue Patent Enlarging Scope of Claims.— No reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent.

ADDENDUM

ADDENDUM TABLE OF CONTENTS

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ANTARES PHARMA, INC.,	)	
Plaintiff,	)	
v.	)	Civ. No. 14-270-SLR
MEDAC PHARMA, INC. and MEDAC GMBH,	)	
Defendants,	)	
and	)	
BECTON DICKINSON FRANCE S.A.S. and BECTON DICKINSON AND COMPANY	)	
Intervenors.	)	

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MEMORANDUM OPINION

Dated: July 10, 2014
Wilmington, Delaware

ROBINSON, District Judge

I. INTRODUCTION

On February, 28, 2014, plaintiff Antares Pharma, Inc. ("Antares") filed a complaint alleging infringement of U.S. Patent Nos. 6,565,553 ("the '553 patent") and 8,480,631 ("the '631 patent") by defendants Medac Pharma, Inc. ("Medac Pharma") and medac GmbH, (collectively "Medac"). (D.I. 1) Antares filed a motion for preliminary injunction directed to the '553 and '631 patents on March 14, 2014. (D.I. 6) On April 18, 2014, Antares amended its complaint, adding allegations of infringement of U.S. Patent Nos. RE 44,846 ("the '846 patent"), and RE 44,847 ("the '847 patent") (collectively with the '553 and '631 patents, "the patents-in-suit"). (D.I. 27) Antares amended its motion for preliminary injunction on the same day to seek an injunction directed at the '846 and '631 patents.[1] (D.I. 29)

On May 5, 2014 Medac Pharma answered the complaint and counterclaimed for invalidity and non-infringement of the patents-in-suit. (D.I. 40) The same day, Becton Dickinson France S.A.S., Becton, Dickinson and Company (collectively "Becton") filed an intervenor complaint seeking a declaratory judgment that no valid claim of the patents-in-suit is infringed by Becton and alleging that the patents-in-suit are invalid. (D.I. 39) On May 30, 2014, Antares answered the intervenor complaint and counterclaimed, alleging that Becton infringes the '553, '846 and '847 patents. (D.I. 52) The same day, Antares also answered Medac Pharma's counterclaims. (D.I. 53) On July 1, 2014, medac GmbH answered Antares' amended complaint and counterclaimed for noninfringement and invalidity of the patents-in-suit. (D.I. 77)

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[1]Replacing the original motion for preliminary injunction.

Presently before the court is Antares' amended motion for preliminary injunction. (D.I. 29) The court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338.

II. BACKGROUND

Antares is a small, publicly traded, U.S.-based developer of automatic injection devices used to self-administer pharmaceuticals. (D.I. 27 at ¶ 2) In October 2013, the FDA approved Otrexup™, which uses Antares' proprietary automatic injection device, and in February 2014, Antares began selling Otrexup™. Otrexup™ is the first and only product approved by the FDA to administer methotrexate subcutaneously (under the skin) to treat rheumatoid arthritis (RA) and psoriasis. (D.I. 30 at 1-2)

Medac Pharma is a newly formed U.S. subsidiary of the German pharmaceutical company, medac GmbH. (D.I. 27 at ¶¶ 3-4) Medac Pharma is an innovator in injectable methotrexate, and its parent, medac GmbH, is the leader in the European market for such products. (D.I. 44 at 6) Medac GmbH commercializes hand-powered pre-filled methotrexate syringes in Europe. (D.I. 44 at 6) On September 10 2013, Medac Pharma submitted a 505(b)(2) application with the FDA for a methotrexate injection product, which will be sold under the trade name RASUVO™. (D.I. 44 at 2)

There are two patents at issue: the '631 patent, titled "Hazardous Agent Injection System," which issued on July 9, 2013; and the '846 patent, titled "Needle Assisted Jet Injector," which issued on April 15, 2014.

III. STANDARD OF REVIEW

A preliminary injunction is "an extraordinary remedy that should only be granted in limited circumstances." *Capriotti's Sandwich Shop, Inc. v. Taylor Family Holdings,*

Inc., 857 F. Supp. 2d 489, 501 (D. Del. 2012). To be successful, a movant at bar must demonstrate: (a) a reasonable likelihood of success on the merits; (b) the prospect of irreparable harm in the absence of the injunction; (c) that this harm would exceed harm to the opposing party; and (d) that granting the injunction is in the public interest. See *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1344 (Fed. Cir. 2008). "If either or both of the fundamental requirements—likelihood of success on the merits and probability of irreparable harm if relief is not granted—are absent, an injunction cannot issue." *Enzo Life Sciences, Inc. v. Adipogen Corp.*, Civ. No. 11–88, 2011 WL 2559610, at *2 (D. Del. June 28, 2011) (citing *McKeesport Hosp. v. Accreditation Council for Graduate Med. Educ.*, 24 F.3d 519, 523 (3d Cir. 1994).

IV. DISCUSSION

A. Likelihood of Success on the Merits

1. The '631 patent

The '631 patent is directed to "a hazardous agent injection system," more specifically "a needle-assisted jet injector." ('631 patent, abstract, col. 45:8-14) The '631 patent distinguishes a "jet injector" (including a "needle-assisted jet injector") and an autoinjector or hand-powered syringe. (Col. 26:49-27:18) Specifically,

> whereas a medicament injected into a subject via an autoinjector or hypodermic syringe is delivered in a bolus near the needle tip, the medicament delivered from a jet injector is sprayed rapidly into the tissue, typically remotely from the needle tip, and typically does not deposit the medicament in a bolus local to a needle tip. . . . Needle-assisted jet injectors . . . have pressures and speeds that are sufficiently high so that the medicament exits the needle tip as a fluid jet.
> . . .
> Because the medicament delivered by a jet injector is essentially sprayed rapidly into the subject's tissue, remotely from the needle tip, the

> medicament does not leave the jet injector as a single drop or bolus and is thus not delivered to a subject as a bolus local to a needle tip. Therefore, by using the jet injectors disclosed herein, a medicament can be dispersed into a subject's tissue more efficiently.

(Col. 27:5-18, 32:54-61)

The court construes "jet-injector" as "a powered injector used to achieve the delivery of medicaments in a high speed stream, that is, at a pressure, force, and speed sufficiently high so that the medicament exits the needle tip as a fluid jet and not as a bolus. The critical difference between a jet injector and autoinjectors or hand-powered syringes is how the medicament is delivered - dispersed remotely from the needle-tip (jet) rather than deposited in a locus near the needle tip (bolus)."

The parties' experts compared injection with a conventional needle to injection with Medac's autoinjector using a ballistics gel block - the still images show a bolus surrounding the end of the needle. (D.I. 11 at ¶ 48; D.I. 50 at ¶ 96) Antares' expert, Fisher, opined that "Medac's methotrexate injector is a jet injection device, because it uses a jet to inject to the medicament into a patient to a depth beyond the tip of the needle." Moreover, Fisher concluded that "when Medac's injector is fired into a block of ballistics gel, the force of the injector causes the fluid to be expelled as a jet that penetrates to a deeper portion of the block, . . . in contrast to the lack of jet . . . [when] firing a manual syringe into the same type of block." (D.I. 11 at ¶ 48) Medac's expert duplicated the ballistics gel study and concluded that "[t]he [M]edac injector . . . deposits methotrexate in a bolus near the needle tip" and "Medac's injector does not have increased dispersion as compared to the hand-powered syringe." (D.I. 50 at ¶¶ 97-98) Neither party presented a comparison of Antares' jet injector with either a hand

syringe or Medac's autoinjector nor did the parties illustrate the "rapid spray" dispersion of a jet injector.[2]

During prosecution, an inventor of the '631 patent submitted a declaration to the PTO emphasizing that

> the subcutaneous deposition of methotrexate resulting from the claimed needle-assisted jet injector is important because increased dispersion of methotrexate, as compared to bolus deposition of methotrexate from a hand-powered needle and syringe, significantly impacts the methotrexate's contact and interactions with cells of the tissue into which it is injected, which in turn alters the migration of the methotrexate to the systemic circulation.

(D.I. 45, ex. 17 at ¶ 12) In contrast, Antares now avers that "increased dispersion" and the creation of a "fluid jet" are only "possible benefits" of the '631 patent. (D.I. 67 at 5, citing col. 27:1-11, 18:43-49)

Antares also argues that "Becton did human injection tests showing that drug was deposited over 17.5 mm beneath the skin with the autoinjector, something a manual injector could not do." (D.I. 67 at 5) Abry, the European Manager for Commercial Development at Becton Dickinson France S.A.S., acknowledged that one "outlier," labeled "statistically outlying values" (in a study with a total of 960 injections), showed drug penetration of 17.5 mm. (D.I. 69, ex. HH at 166:10-18) However, the results of the study "demonstrated that there was no significant difference in depth of the fluid depot between Physioject™[3] autoinjection and a manual syringe injection, finding . . .a mean depth of fluid depot of 7.75 mm for self-injection and of 7.83 mm for

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[2]With the exception of a hand drawing provided in Medac's presentation to the court.

[3]Becton's disposable autoinjector.

nurse-assisted manual injection for the 0.2 mL injections, and of 8.58 mm for self-injection and of 8.72 mm for nurse-assisted manual injection for the 1.0 mL injections." (D.I. 49 at ¶¶ 11-12, ex. A at 393, fig. 2) Similarly reported data in a Becton document "include[d] an exemplary echography of the tissue taken during the study and report[ed] that the depth of depot 'was statistically not different between the auto-injector (8.2 mm; SD: 2.5) and the prefilled syringe as alone (8.3 mm; SD: 2.2).'" (D.I. 49 at ¶ 13, ex. C at MEDAC-DE 2616)

The '631 patent specification differentiates jet injectors as providing increased dispersion and not depositing medicament in a bolus. Indeed, the patentees focused on this difference during prosecution. Moreover, Antares has not offered a comparison of its jet injector with Medac's autoinjector. Further, the still image provided of Medac's autoinjector shows a bolus near the needle tip. The court concludes that Antares has not carried its burden of showing a likelihood of success on the merits.[4]

2. The '846 patent

a. Prosecution history

The '846 patent is a reissue of U.S. Patent No. 7,776,015 ("the '015 patent"), which issued on August 17, 2010 from Appl. No. 11/002,687 ("the '687 application") filed on December 3, 2004. The '846 patent, titled "Needle Assisted Jet Injector," is described in the "Summary of Invention" as relating to "a needle assisted jet injector." (Col. 2, 54-55) In the "Background of the Invention," the patentees described the

[4]Therefore, the court does not reach Medac's invalidity arguments.

following needs that were being addressed in the field of invention,[5] that is,

> a need for a needle assisted jet injector that operates at relatively low pressure and that is capable of quickly delivering medicament. There also exists a need for such an injector having a retractable or concealed needle to prevent the medical hazards associated with exposed needles.

(Col. 2:45-50)

During prosecution, the examiner rejected the '687 application as anticipated and/or made obvious by prior art references that, according to the applicants, did not disclose a "jet injector." The following are just a few examples of the applicants' arguments in this regard:

> In the Response to Arguments section of the Office Action, the statement is made that it is allegedly "clear" that Kramer injects liquid as forcefully shooting forth from a nozzle in a stream, and that this makes Kramer a jet injector. Furthermore, the Office Action separated the term "jet" from "injection," improperly treating them as separate terms. Such a definition is improper and is contrary to the ordinary understanding in the art. The terms "jet injector," "jet injecting," "jet injection," and related phrases are well understood terms of art. The jet from a jet injector is powerful enough to penetrate through a depth of tissue, such as muscle or skin layers, instead of being deposited as a bolus. Jet injectors are often defined in terms of the combination of certain parameters like pressures, diameter of the outlet that makes the jet, and flow rate, but Kramer does not disclose these parameters to suggest a jet.
>
> * * * *
>
> With regard to the recitation of the jet injection device itself, the Examiner argued that this recitation in the preamble was not given patentable weight and cited 1976 and 1951 case law in alleging that the term "jet injector" somehow merely relates to an intended use. The recitation of "A jet injector" is definitely structural and significantly affects the structural recitations in the body of the claim. One of ordinary skill in the art would have understood that a jet injector involves significant structural features, including, for instance,

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[5] "The present invention is directed to a device for delivery of medicament, and in particular to a jet injector with a short needle to reduce the pressure at which the jet injector must eject the medicament for proper delivery." (Col. 1:24-27)

> sufficiently powerful force-generating source, a construction that can withstand high pressures of jet injectors, and a suitable orifice such as the orifice of the injection-assisting needle to produce the jet that is understood to be powerful enough to penetrate through tissue as a jet. **Several elements recited in the claim, such as the force-generating source and the needle, would have a different construction in a jet injector than in other types of injectors, such as hypodermic or auto-injectors, which are described in the specification, or such as the injector of Kramer**. Consequently, the term, "jet injection device," in the preamble is a positive recitation from which the structures of the claim body depend.

(D.I. 45, ex. 9 at 2-3) (emphasis added) (*see also* D.I. 45, ex. 20 at 5-6)

In June 2006 and October 2008, the applicants were still attempting to overcome the examiner's rejections under 35 U.S.C. §§ 102 and 103 over such prior art references as Kramer, arguing that "the jet injector of the present claims" is "significantly different" from the "automated injector of Kramer." (*Id.*, ex. 27 at 8) In order to "further define the invention and distinguish it from Kramer in view of all previously submitted reasons," the applicants amended independent claims 1 and 21 to add the descriptive language in bold:

> wherein the force generating source is configured such that activation of the force generating source moves the plunger to apply a pressure to the medicament in the fluid chamber . . . to expel medicament from the fluid chamber **by creating a high-speed jet of the medicament that penetrates patient tissue to a distance through and beyond[6]** . . . the injecting end **and past the insertion point to an injection site**.

(*Id.*, ex. 27 at 3, 7) The examiner issued a notice of allowance on April 6, 2010, explaining that

> [t]he claims in this application have been allowed because the prior art of record fails to disclose either singly or in combination the claimed apparatus of a jet injection device with the high speed jet with a fluid pressure between about 100 and 1000 p.s.i. to penetrate tissue through

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[6]Replacing the phrase "and eject the amount of the medicament through."

> and axially beyond the insertion point and such that the injecting end reaches a needle point at a depth of up to about 5mm below the surface along (or no more [than] 5mm) along with a mechanical member that is elastically deformed to provide the force.
>
> The closest prior art is Brennen (U.S. Patent 4,222,392), Baum (U.S. Patent 4,929,238), Kramer (U.S. Patent 5,176,643) and Haber (U.S. Patent 5,304,128), but all fail to disclose the claimed combination with the claimed penetration depth, pressure p.s.i. output, axial penetration, and elastically deformed mechanical force.

(*Id.*, ex. 28 at 2) The '687 application issued as the '015 patent on August 17, 2010.

On June 22, 2012, Appl. No. 13/531,023 was filed by the inventors of the '015 patent, presumably seeking to amend such pursuant to 35 U.S.C. § 251(a).[7] According to the record presented by the parties, new claims 23-37 were added, reciting "an injection device" comprising certain features. In responding to rejection of certain of the new claims by the examiner in September 2013, the applicants argued that neither Kramer nor any of the other cited references, alone or in combination, suggested or taught either of a "latch or spring feature, or equivalent structures, within the proximal end" of the "injecting device that is under sufficient compression to eject the medicament . . . ." (*Id.*, ex. 24 at 11, 13) The applicants remarked that "support" for the new claims could be found "throughout the specification and in particular the paragraphs (based on the column and line numbers of U.S. Patent No. 7,776,015, the basis of the current reissue application) and figures" enumerated by the applicants. (*Id.*, ex. 24 at 9) The '846 patent issued on April 15, 2014.

b. Legal standard

[7]"Presumably" is used because the parties did not see fit to include such in the record, at least not where it could be easily found by the court.

Section 251(a) of Title 35 of the United States Code provides in relevant part as follows:

> Whenever any patent is, through error, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue.

The Federal Circuit has found two requirements in § 251(a). The first, the "error" requirement, "limits the availability of a reissue patent to certain correctable errors," e.g., "the patentee claiming his invention too broadly or too narrowly." *Hester Indus. Inc. v. Stein Inc.,* 142 F.3d 1472, 1479 (Fed. Cir. 1998) (citation omitted). "The 'original patent' requirement is a second and independent requirement, . . . which restricts a reissue patent to 'the invention disclosed in the original patent.'" *Id.* (citation omitted). The reissue statute should be construed liberally, as it is "based on fundamental principles of equity and fairness . . . ." *In re Weiler*, 790 F.2d 1576, 1579 (Fed. Cir. 1986).

With respect to the "error" requirement, "[o]ne of the most commonly asserted 'errors' in support of a broadening reissue is the failure of the patentee's attorney to appreciate the full scope of the invention during the prosecution of the original patent application." *Hester*, 142 F.3d at 1479. In determining whether such an error actually supports the new claims, a review of the prosecution history of the original patent must be undertaken to ensure that a patentee does not regain "'through reissue . . . subject matter that he surrendered in an effort to obtain allowance of the original claims.'" *Id.* at

1480 (citation omitted). The "recapture rule" addresses the above concern.

As explained by the Federal Circuit in *Hester*,

> "[u]nder [the recapture] rule, claims that are 'broader than the original patent claims in a manner directly pertinent to the subject matter surrendered during prosecution' are impermissible.". . . Application of the recapture rule begins with a determination of whether and in what respect the reissue claims are broader than the original patent claims. . . . A reissue claim that does not include a limitation present in the original patent claims is broader in that respect. . . .

Id. If the reissue claims are determined to be broader, under the recapture rule the court must "next examine whether these broader aspects relate to surrendered subject matter. . . . 'To determine whether an applicant surrendered particular subject matter, [the court] look[s] to the prosecution history for **arguments** and changes to the claims made in an effort to overcome a prior art rejection.'" *Id.* (citation omitted) (emphasis in original).

> [A]s a general proposition, in determining whether there is a surrender, the prosecution history of the original patent should be examined for evidence of an admission by the patent applicant regarding patentability. . . . In this regard, claim amendments are relevant because an amendment to overcome a prior art rejection evidences an admission that the claim was not patentable. . . .
>
> Arguments made to overcome prior art can equally evidence an admission sufficient to give rise to a finding of surrender.

Id. at 1481. If the court concludes that there has been a surrender, it "must next determine whether the surrendered subject matter has crept back into the asserted reissue claims." *Id.* at 1482.

If the above described prongs of the recapture rule have been satisfied, the rule can be avoided only if the reissue claims "are materially narrower in other overlooked aspects of the invention. The purpose of this exception to the recapture rule is to allow

the patentee to obtain through reissue a scope of protection to which he is rightfully entitled for such overlooked aspects." *Id.* at 1482-83. Therefore, "[u]nless the claims are materially narrowed in a way that avoids substantial or whole recapture of the surrendered subject matter, the surrendered subject matter has crept into the reissue claims and they are barred under the recapture rule." *In re Youman*, 679 F.3d 1335, 1344-45 (Fed. Cir. 2012).

c. Analysis

Although it is not clear to the court that the parties provided the entire prosecution history of either the '015 patent or the '846 patent in connection with the instant preliminary injunction proceeding, the court has reviewed the record as submitted and concludes that the recapture rule applies to the facts at bar, despite plaintiff's arguments to the contrary: "There are two different claimed aspects, the 'jet' aspect in the original application and the safety features aspect in the reissue. . . . As Medac's expert admitted, the claim 31 safety features can be used with any autoinjector, not just jet injectors. . . . In this situation, . . . '[a]s for obtaining claims on reissue which are different, no prohibition arises merely because of the language of the reissue statute.'" (D.I. 67 at 4, citing *In re Wadlinger*, 496 F.2d 1200, 1207 (C.C.P.A. 1974))

The court respectfully disagrees with plaintiff's reasoning. The prosecution history of the '015 patent is replete with arguments and amendments made to distinguish such prior art references as Kramer, wherein the distinguishing feature of the invention was characterized as a "jet injector." Indeed, the applicants argued in this regard that the structural recitations in the original claims were affected by the fact that

it was a "jet injection device" that was claimed; to wit, "the term, 'jet injection device,' in the preamble is a positive recitation from which the structures of the claim body depend." (D.I. 45, ex. 9 at 3) On multiple occasions, the applicants argued that "the jet injector of the present claims" is "significantly different" from the automated injector of Kramer. (*Id.*, ex. 27 at 8) The applicants amended claims 1 and 21 to further buttress the fact that their invention was different from other injectors, in that the medicament was expelled "from the fluid chamber **by creating a high-speed jet of the medicament** . . . ." (*Id.*, ex. 27 at 3, 7) Each of the original 22 claims refers to a "jet injection device," and the specification is written in the context of a "jet injection device."[8]

Applying the recapture rule to the above facts, the reissue claims are broader, in that they do not recite the limitation "jet injection device" but, rather, "an injection device." Given the prosecution history related above, there is every indication that the applicants surrendered all injectors but for "jet injectors," understood by those of skill in the art at the time to include only those injectors having a "jet . . . powerful enough to penetrate through a depth of tissue, such as muscle or skin layers, instead of being deposited as a bolus." (*Id.*, ex. 9 at 2) Likewise, the applicants argued that "jet injectors" affected the structural recitations in the body of the original claims[9] and, as noted, the structural features now claimed in the '846 patent were described in the specification of the '015 patent only in the context of a jet injector. Without the

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[8]The specification and the claims mention "jet injection," "jet injector," and like phrases over 75 times.

[9]*See, e.g.*, D.I. 45, ex. 9 at 2-3.

structural context of a jet injector, the court concludes that the surrendered subject matter - prior art injectors that would not be considered "jet injectors" to those of skill in the art at the time - has crept into the reissue claims.[10]

With respect to the final prong of the analysis, that is, whether the recapture rule can be avoided because the applicants did not recapture everything they surrendered, the analysis proceeds on a limitation-by-limitation basis. *See North American Container, Inc. v. Plastipak Packaging, Inc.*, 415 F.3d 1335, 1350 (Fed. Cir. 2005). To avoid recapture for claims that are broader in some respects and narrower in others,[11] "the narrowing must relate to the subject matter surrendered during the original prosecution . . . ." *In re Mostafazadeh*, 643 F.3d 1353, 1359 (Fed. Cir. 2011). Here, the "jet injector" and needle length limitations of the claims were entirely eliminated on reissue and no new restriction was imposed on the injector or needle that would avoid the recapture rule.

d. Conclusion

The '015 patent claimed certain features of a "jet injector." The '015 patent issued over prior art references that arguably disclosed those same features but in a different injector. The patentees ultimately prevailed in convincing the examiner that the "jet injector," as known to those of skill in the art, had distinct characteristics and

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[10]To the extent that the structural limitations of the reissue claims only make sense in the context of a jet injector, e.g., a syringe does not require a spring or a latch, then the court construes "an injecting device" consistent with its construction of "jet injector" in the '631 patent and relies on the related infringement analysis *supra*.

[11]By adding the "latch" limitation, e.g., the asserted claims are arguably narrower than the original claims.

structure not found in the cited prior art. To allow the patentees to remove this limitation and claim features that were only described in the context of a jet injector does not fit within the realm of corrections contemplated within § 251. As discussed above in the analysis of the '631 patent, Antares has not carried its burden of showing likelihood of success on the merits that Medac's product infringes claims directed to a "jet injector."

B. Irreparable Harm

Antares' currently has the only available subcutaneous injector for methotrexate on the market, with Medac set to launch its competing product as early as July 10, 2014. (D.I. 8 at ¶ 14; D.I. 30, exs. F, EE at 14) Insurance companies and other third party payors place drugs into formulary "tiers," which determine the level of co-pays and reimbursements. This impacts the sales of the drug and a company's ability to grow the market. Otrexup™ is now a "tier 3" product, which allows for substantial insurance coverage. (D.I. 8 at ¶¶ 27-28) Antares argues that the launch of a competing product would force the renegotiating of the current tier and pricing structure. Moreover, Antares has identified the types of harm that traditionally have qualified as not easily compensable by money damages—price erosion and threatening its brand. *See, e.g., Aria Diagnostics, Inc. v. Sequenom, Inc.*, 726 F.3d 1296, 1304 (Fed. Cir. 2013) ("Price erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm.") (quoting *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012)). While Medac responds that any losses to Antares are measurable and would be compensable by money damages, the court finds Antares' reasoning more persuasive on this issue, particularly with respect to

the tier pricing. *See, e.g., Nutrition 21 v. U.S.*, 930 F.2d 867, 872 (Fed. Cir. 1991) (stating that some evidence and reasoned analysis for the inadequacy of money damages should be proffered.) Antares has carried its burden of demonstrating irreparable harm.

C. Balance of Harms and Public Interest

While Antares' sales would suffer if Medac's product were introduced and later found infringing, delaying Medac's launch would also cause monetary damages. The balance of harms is neutral. As to the public interest, Antares avers that its product is available and in use for the same indications as Medac's product, i.e., rheumatoid arthritis and psoriasis. Medac responds that the products are not interchangeable as RASUVO™ provides additional dosing flexibility not offered through OTREXUP™. As over 90% of prescribed doses are for the standard doses that Antares already sells, this factor is neutral.

V. CONCLUSION

On the record presented, the court denies Antares' motion for a preliminary injunction. An order shall issue.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ANTARES PHARMA, INC.,	)	
Plaintiff,	)	
v.	)	Civ. No. 14-270-SLR
MEDAC PHARMA, INC. and MEDAC GMBH,	)	
Defendants,	)	
and	)	
BECTON DICKINSON FRANCE S.A.S. and BECTON DICKINSON AND COMPANY	)	
Intervenors.	)	

ORDER

At Wilmington this 10th day of July, 2014, consistent with the memorandum that issued this same date;

IT IS ORDERED that Antares' amended motion for a preliminary injunction (D.I. 29) is denied.

United States District Judge

The United States of America

The Director of the United States Patent and Trademark Office

Has received an application for the reissue of a patent. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a reissue patent on the invention shall be granted under the law.

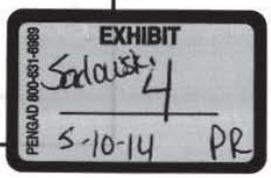
Therefore, this

United States Patent

Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America, and if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States of America, or importing into the United States of America, products made by that process, for the unexpired part of the term of the original grant, subject to the payment of maintenance fees as provided by 35 U.S.C. 41(b). See the Maintenance Fee Notice on the inside of the cover.

Michelle K. Lee

Deputy Director of the United States Patent and Trademark Office



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MAINTENANCE FEE NOTICE

If the application for the original patent being reissued is a utility application filed on or after December 12, 1980, maintenance fees are due three years and six months, seven years and six months, and eleven years and six months after the date of the grant of the original patent, or within a grace period of six months thereafter upon payment of a surcharge as provided by law. The amount, number and timing of the maintenance fees required may be changed by law or regulation. Unless payment of the applicable maintenance fee is received in the United States Patent and Trademark Office on or before the date the fee is due or within a grace period of six months thereafter, the patent will expire as of the end of such grace period.

No maintenance fees are required in plant or design patents.

ANT-DEL00258739

US00RE44846E

(19) **United States**
(12) **Reissued Patent**
Sadowski et al.

(10) **Patent Number: US RE44,846 E**
(45) **Date of Reissued Patent: Apr. 15, 2014**

(54) **NEEDLE ASSISTED JET INJECTOR**

(75) Inventors: **Peter L. Sadowski**, Woodbury, MN (US); **David M. Deboer**, Grand Rapids, MI (US); **Claude L. Berman**, Effingham, NH (US); **Paul R. Lesch, Jr.**, Lino Lakes, MN (US); **Margaret L. Holland**, New Haven, CT (US)

(73) Assignee: **Antares Pharma, Inc.**, Ewing, NJ (US)

(21) Appl. No.: **13/531,023**

(22) Filed: **Jun. 22, 2012**

Related U.S. Patent Documents

Reissue of:
(64) Patent No.: **7,776,015**
Issued: **Aug. 17, 2010**
Appl. No.: **11/002,687**
Filed: **Dec. 3, 2004**

U.S. Applications:
(60) Division of application No. 10/861,429, filed on Jun. 7, 2004, now Pat. No. 7,744,582, which is a division of application No. 09/779,603, filed on Feb. 9, 2001, now Pat. No. 6,746,429, which is a continuation of application No. PCT/US99/17946, filed on Aug. 10, 1999.

(60) Provisional application No. 60/096,464, filed on Aug. 11, 1998.

(51) **Int. Cl.**
A61M 37/00 (2006.01)

(52) **U.S. Cl.**
USPC **604/131**; 604/68; 604/133

(58) **Field of Classification Search**
USPC 604/131–137, 890.1, 192–198, 110, 604/218–231
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,866,458	A	12/1958	Hein, Jr.	
4,222,392	A	9/1980	Brennan	
4,378,015	A *	3/1983	Wardlaw	604/137
4,553,962	A	11/1985	Brunet	
4,790,824	A	12/1988	Morrow et al.	

(Continued)

FOREIGN PATENT DOCUMENTS

WO	9714455	4/1997
WO	9903521	1/1999
WO	9922790	5/1999

OTHER PUBLICATIONS

Hingson, Robert A. et al., "A Survey of the Development of Jet Injection in Parenteral Therapy", Current Researchers in Anesthesia and Analgesia, Official Organ of the International Anesthesia Research Society, vol. 31, No. 6 pp. 361-366 (1952).

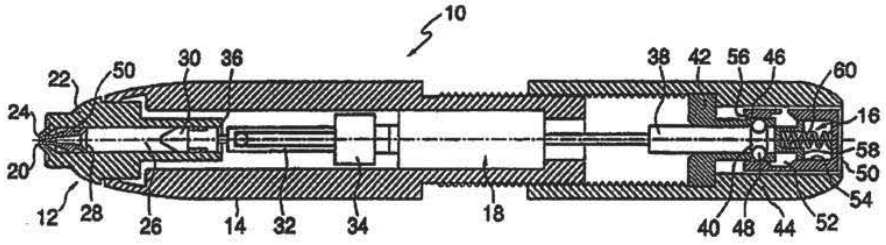
(Continued)

Primary Examiner — Kevin C Sirmons
Assistant Examiner — Phillip Gray
(74) *Attorney, Agent, or Firm* — Morgan, Lewis & Bockius, LLP

(57) **ABSTRACT**

A jet injection device with a fluid chamber in a housing member for holding about 0.02 ml to about 3 ml of a medicament. An injection-assisting needle has an injection end that extends from the housing for inserting into a patient to a depth of up to about 5 mm. A force-generating source is configured to apply a pressure reaching about 100-1000 psi to the medicament in the chamber to expel the medicament through the injecting end of the needle.

37 Claims, 26 Drawing Sheets



(56) **References Cited**

U.S. PATENT DOCUMENTS

4,929,238	A		5/1990	Baum
5,062,830	A		11/1991	Dunlap
5,137,516	A		8/1992	Rand et al.
5,176,643	A	*	1/1993	Kramer et al. 604/135
5,295,965	A		3/1994	Wilmot
5,304,128	A		4/1994	Haber et al.
5,599,302	A		2/1997	Lilley et al.
5,769,138	A		6/1998	Sadowski et al.
6,056,716	A		5/2000	D'Antonio et al.
6,689,092	B2		2/2004	Zierenberg et al.
6,767,336	B1		7/2004	Kaplan
6,805,686	B1		10/2004	Fathallah et al.
7,449,012	B2		11/2008	Young et al.
7,794,432	B2		9/2010	Young et al.
8,048,035	B2		11/2011	Mesa et al.
2005/0020979	A1		1/2005	Westbye et al.
2010/0318037	A1		12/2010	Young et al.
2011/0137247	A1		6/2011	Mesa et al.
2012/0046609	A1		2/2012	Mesa et al.

OTHER PUBLICATIONS

Hingson, Robert A. et al., "Clinical Studies with Jet Injection, A New Method of Drug Administration", Current Researchers in Anesthesia and Analgesia, Official Organ of the International Anesthesia Research Society, vol. 26, No. 6,pp. 221-230, (1947).

* cited by examiner

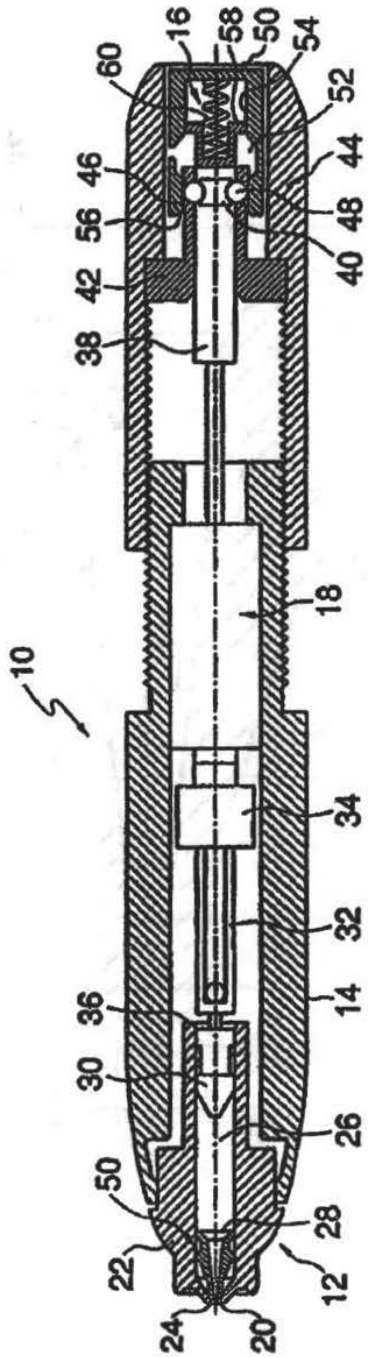


Fig. 1

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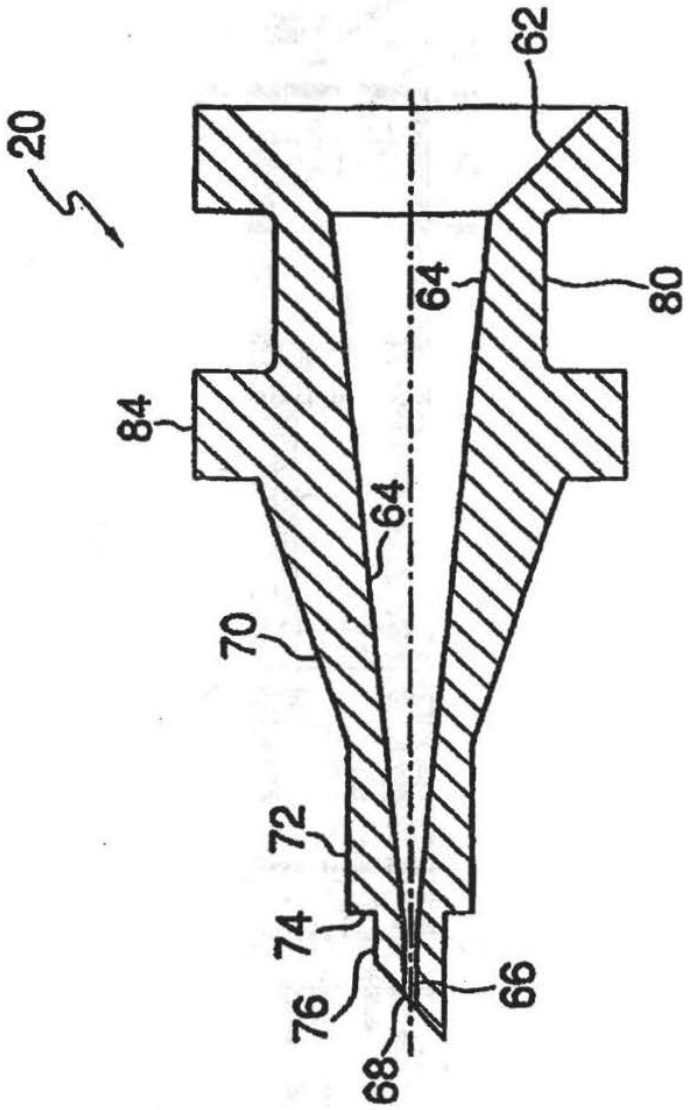

Fig. 2

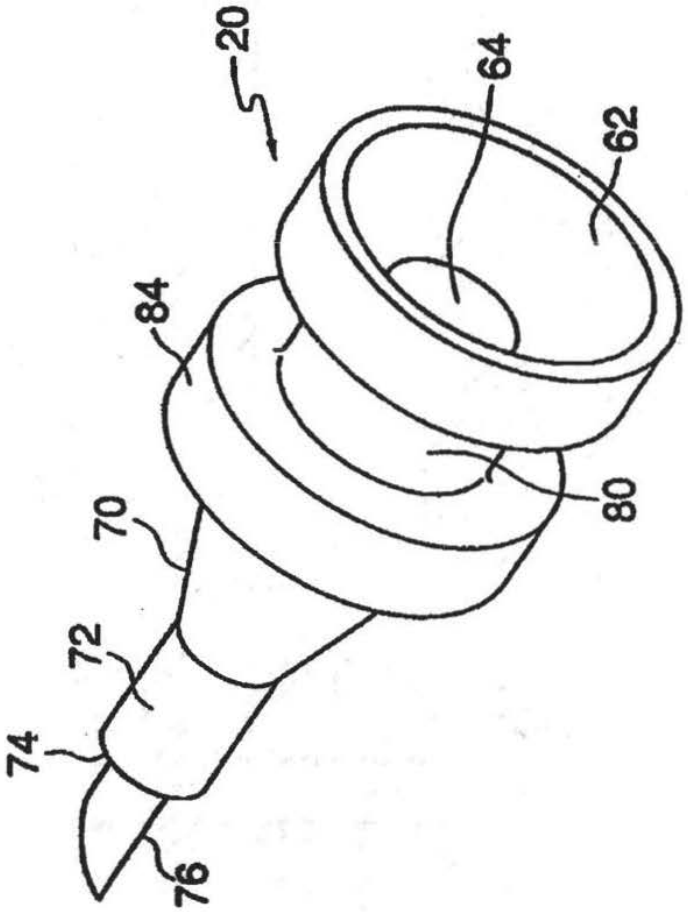

Fig. 3

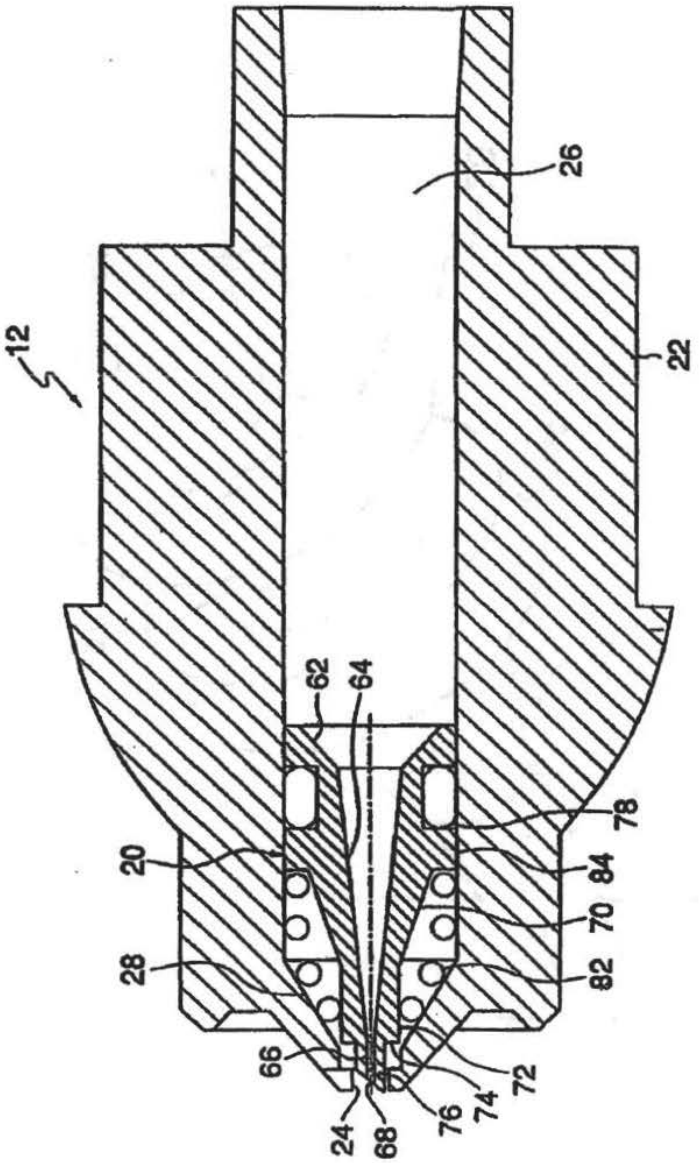

Fig. 4

ANT-DEL00258745

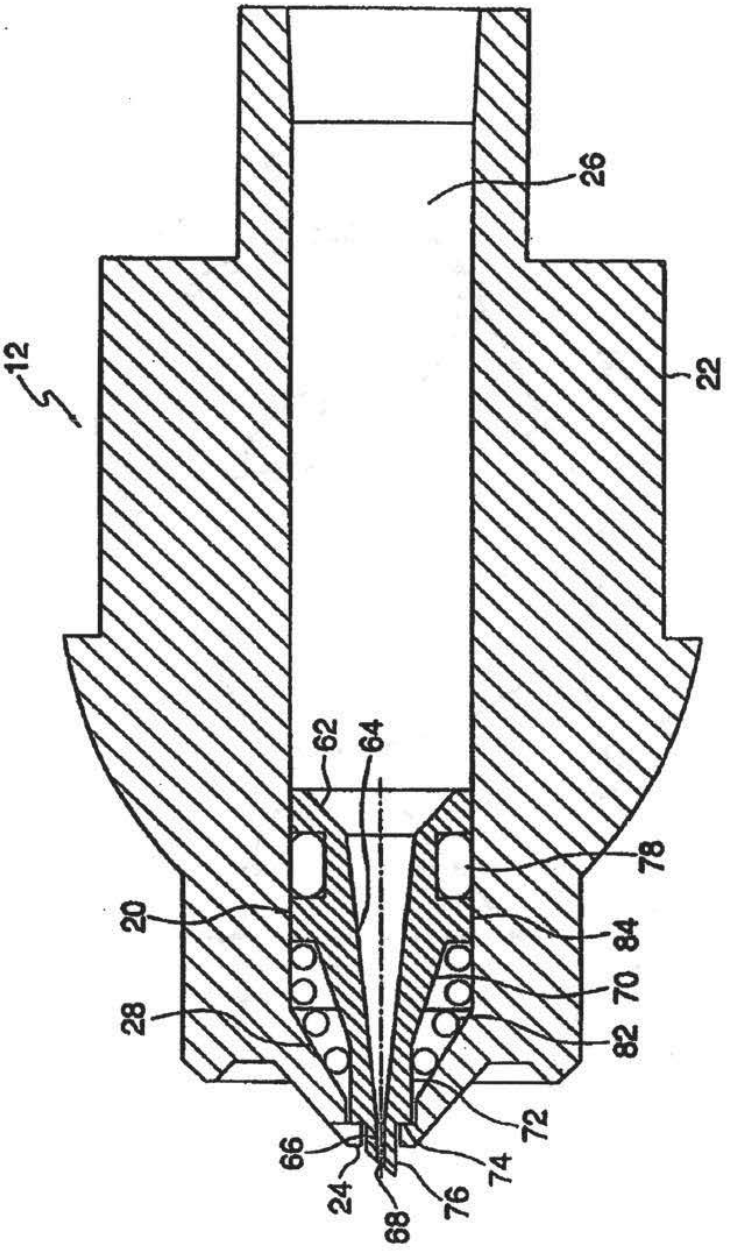

Fig. 5

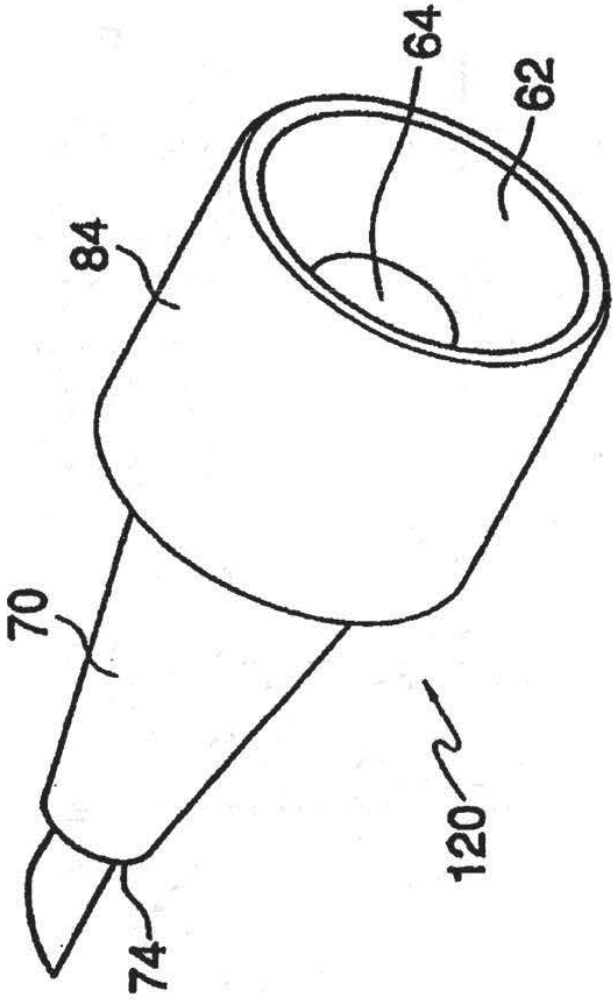

Fig. 6

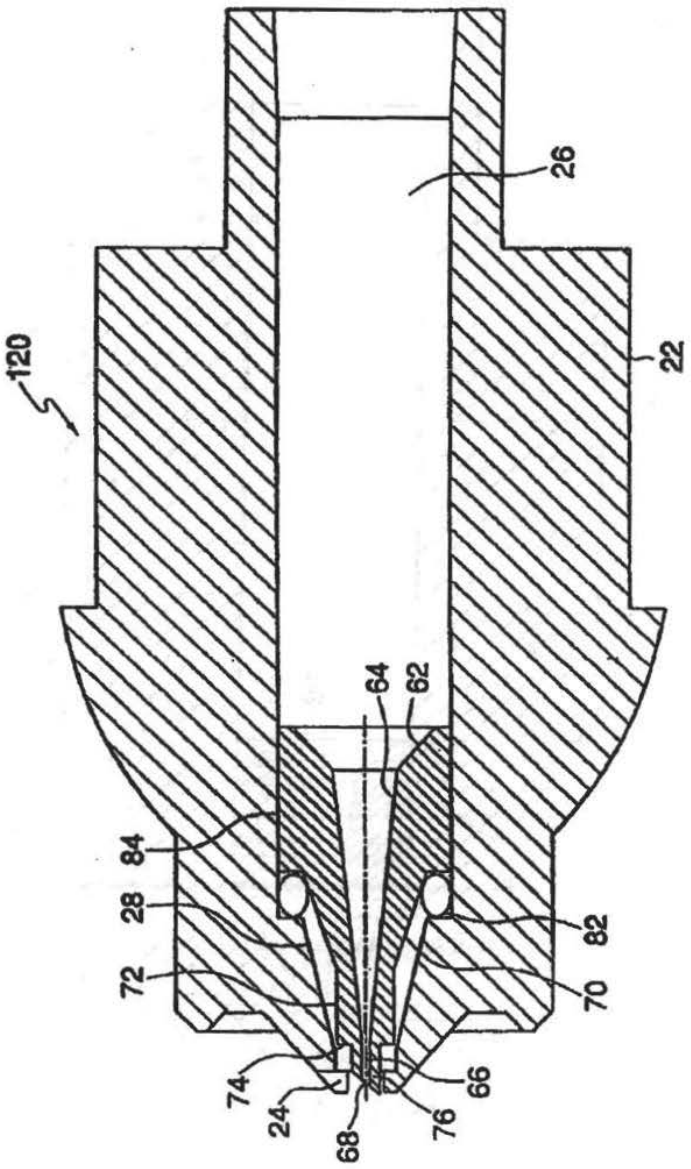

Fig. 7

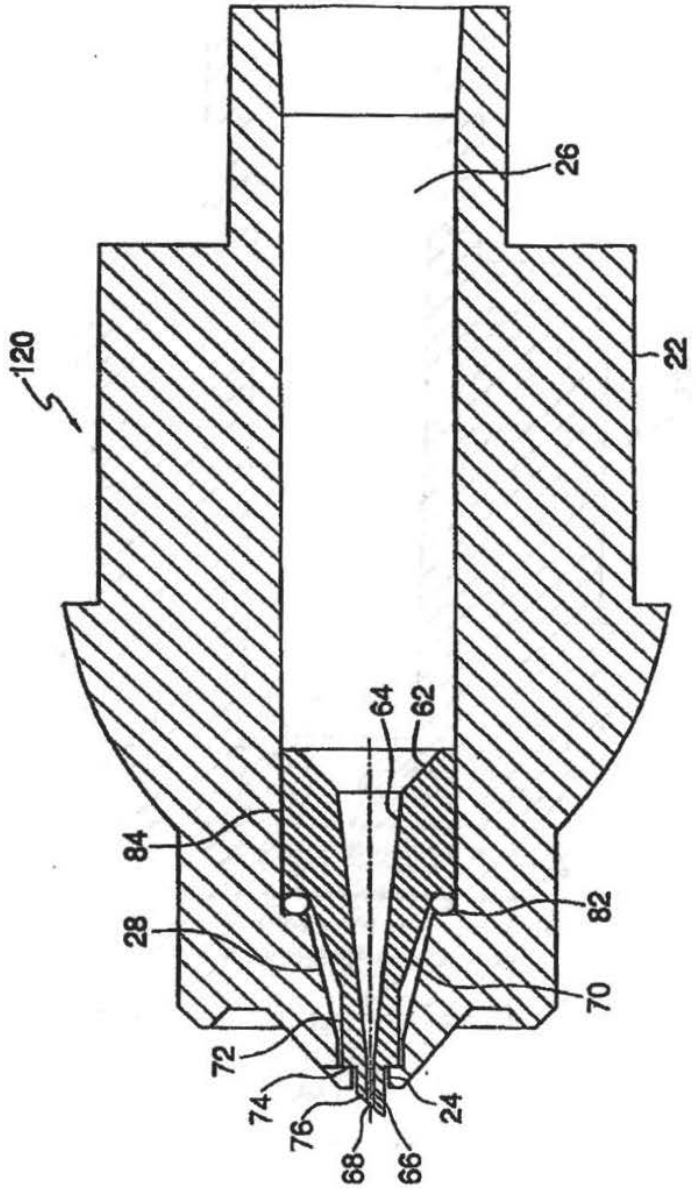

Fig. 8

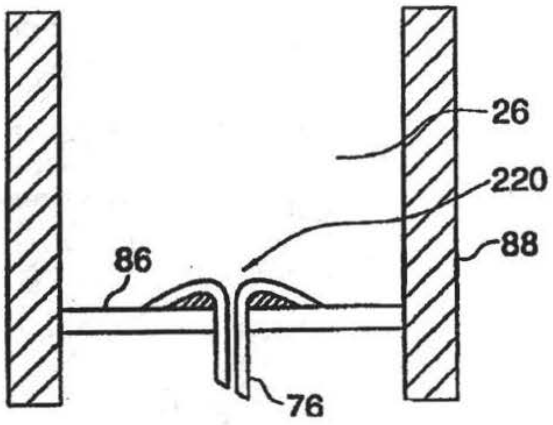

Fig. 9

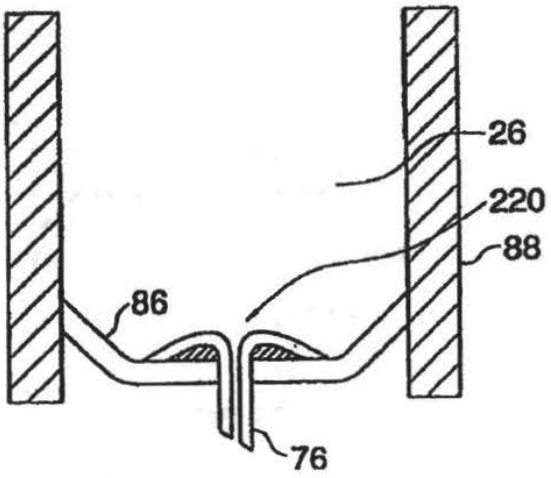

Fig. 10

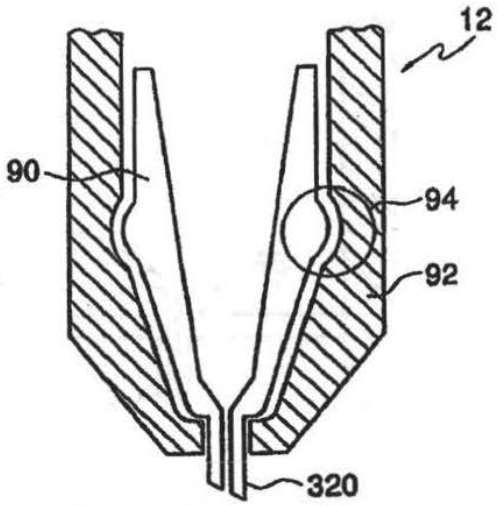

Fig. 11

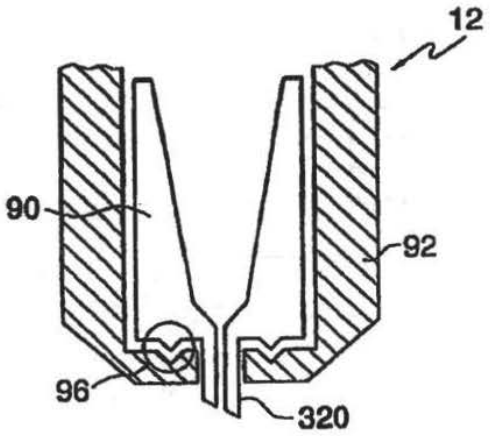

Fig. 12

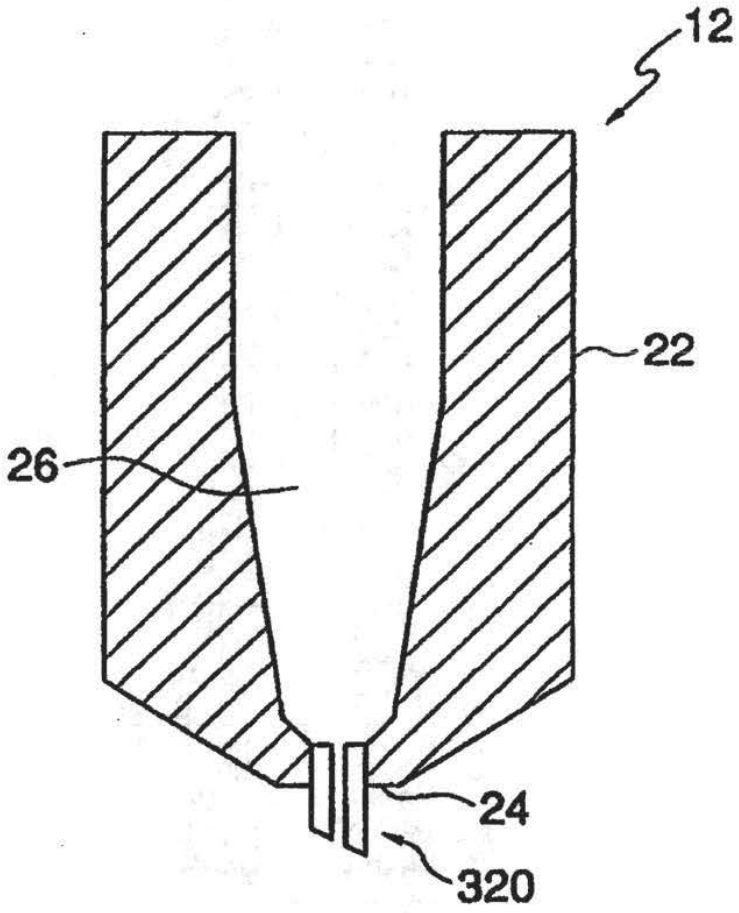

Fig. 13

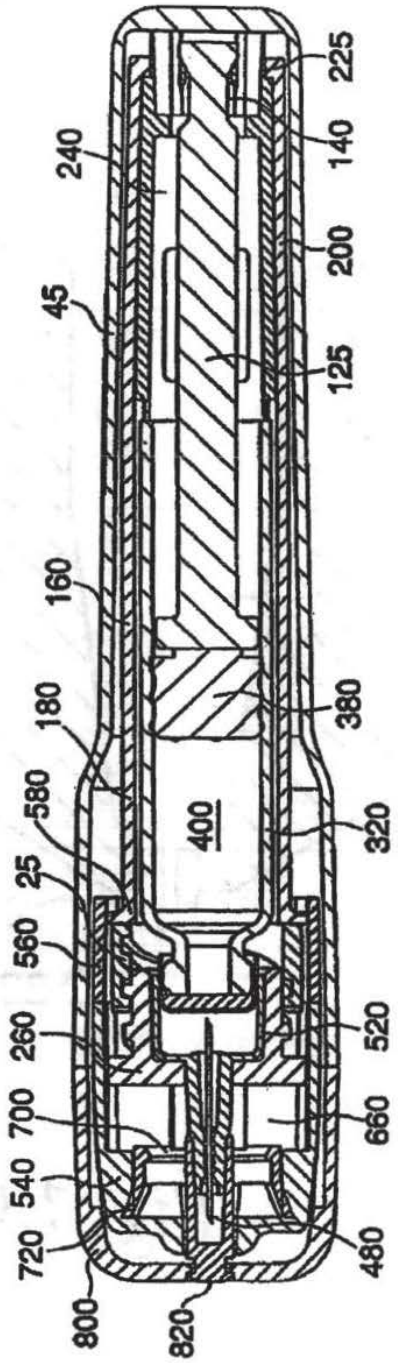

Fig. 14A

ANT-DEL00258753

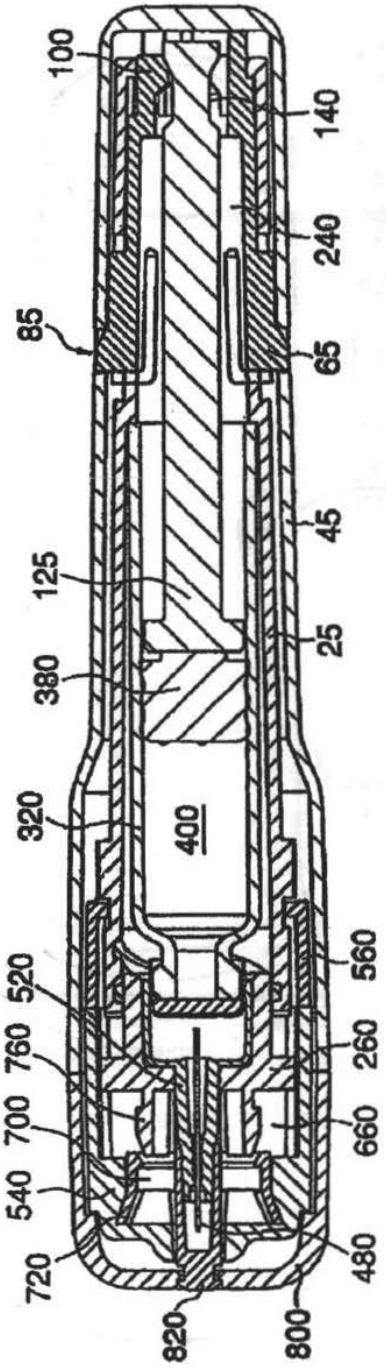

Fig. 14B

ANT-DEL00258754

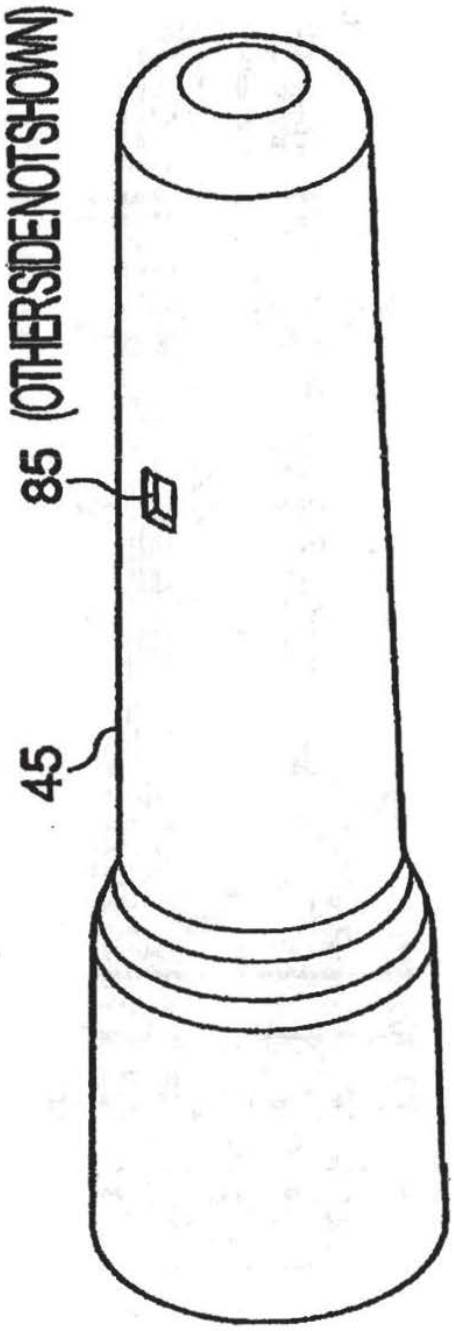

Fig. 15

ANT-DEL00258755

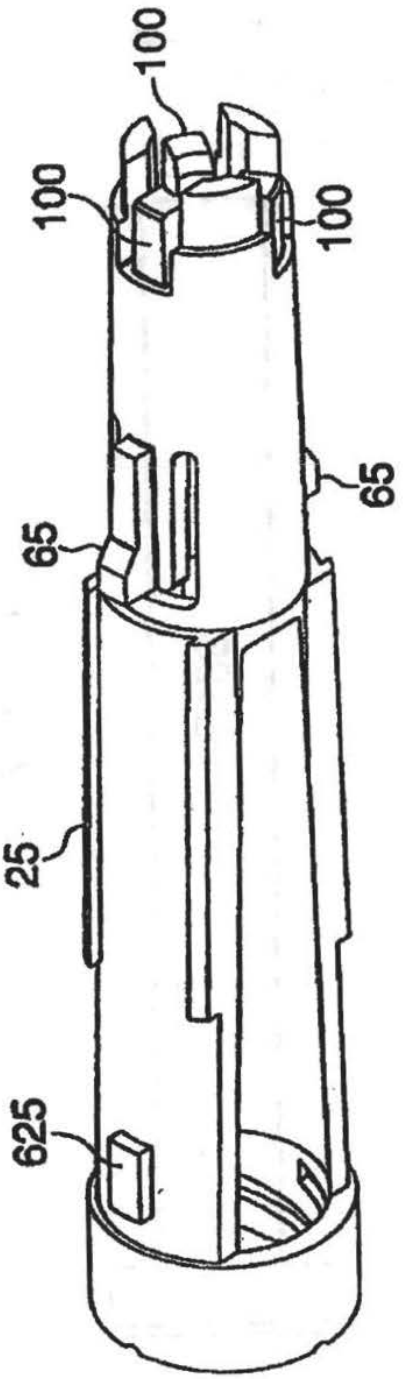

Fig. 16

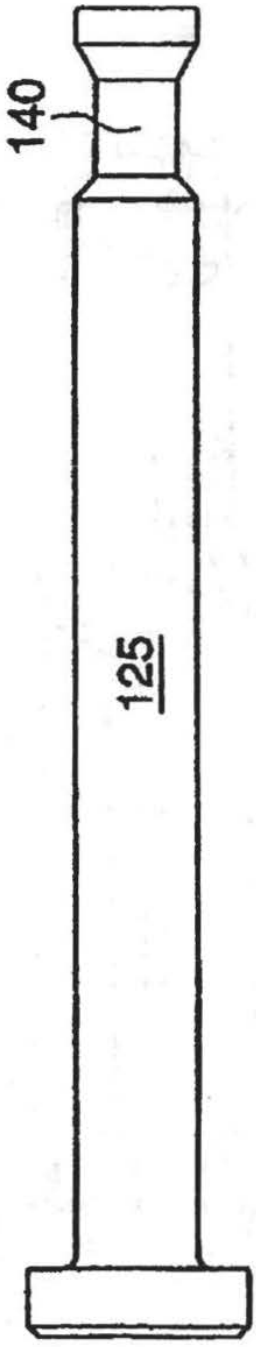

Fig. 17

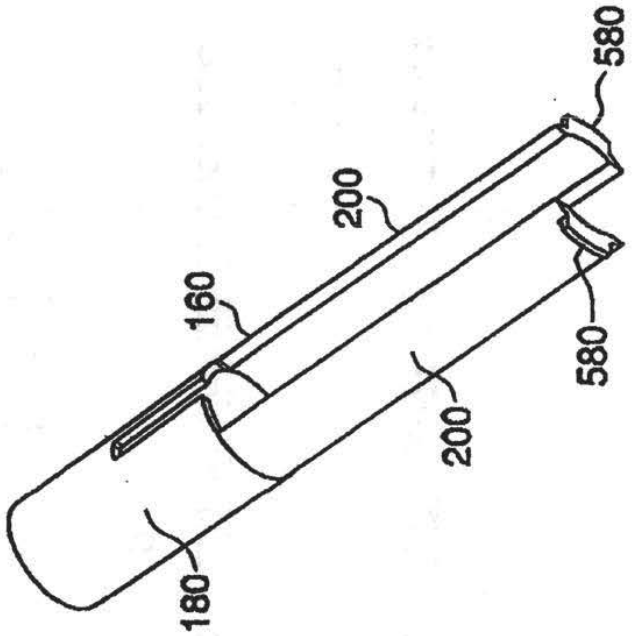

Fig. 18A

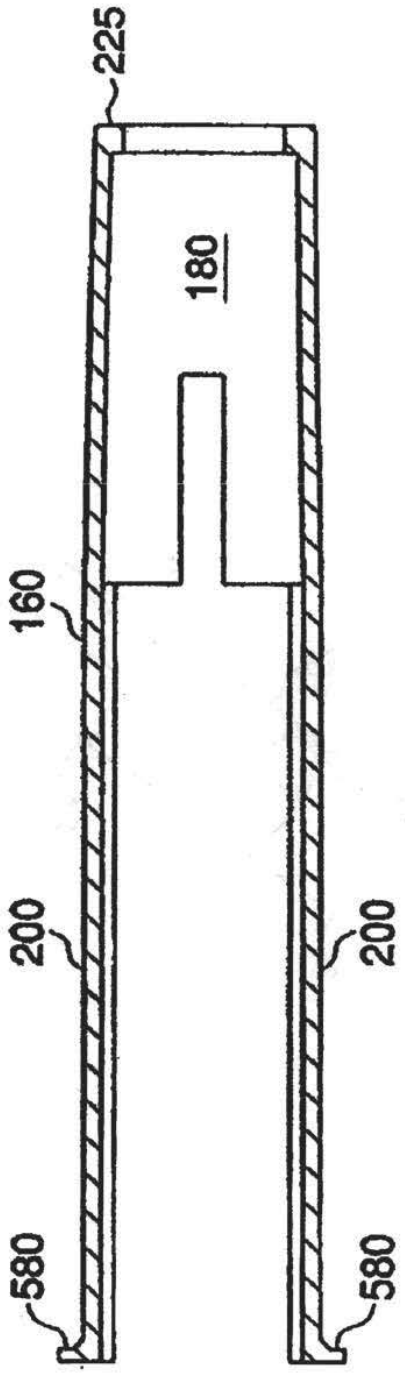

Fig. 18B

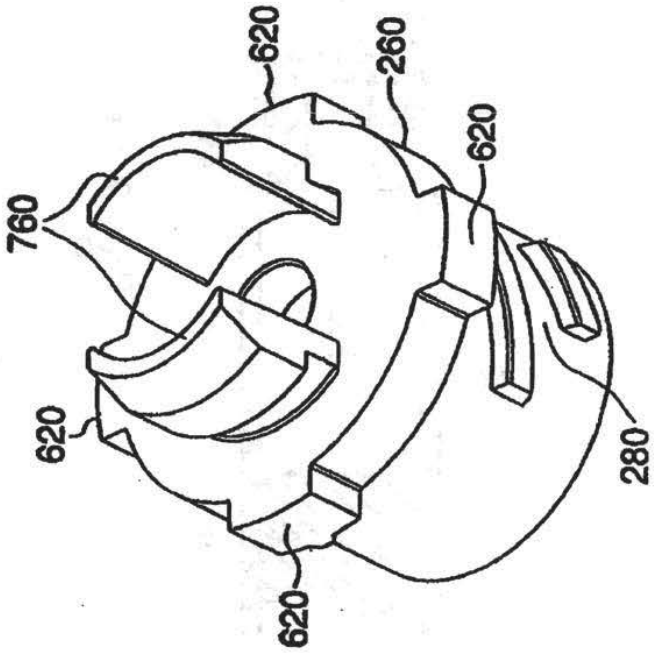

Fig. 19

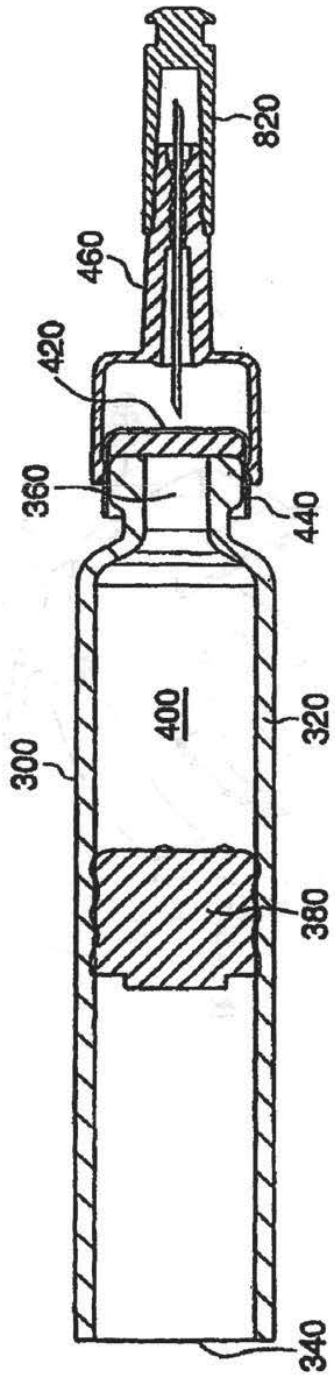

Fig. 20A

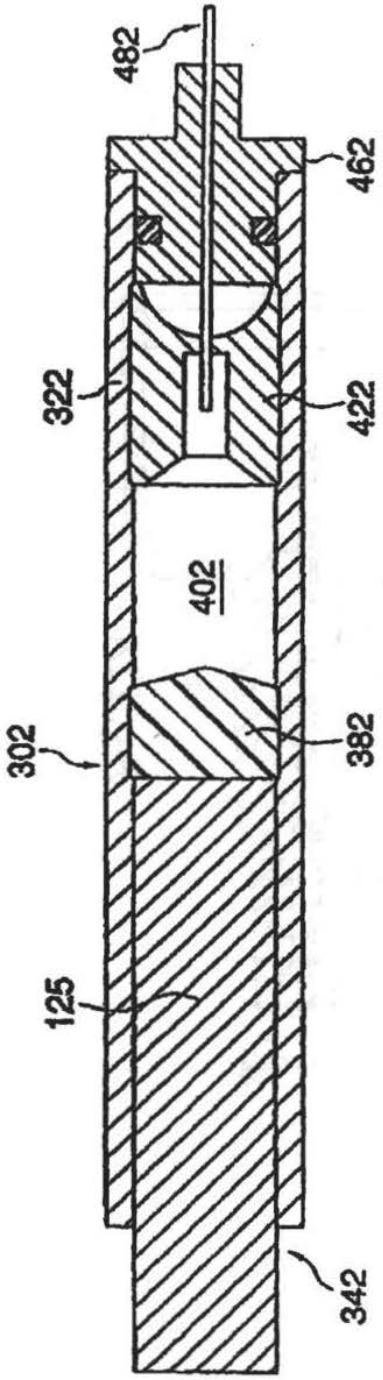

Fig. 20B

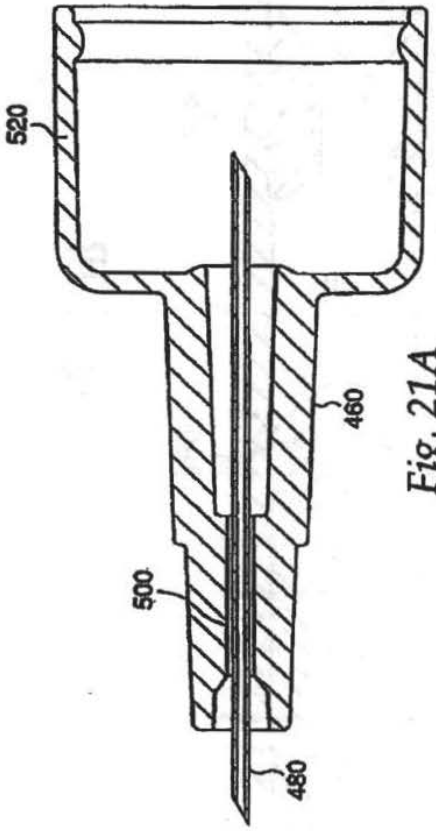

Fig. 21A

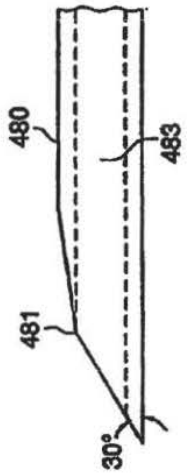

Fig. 21B

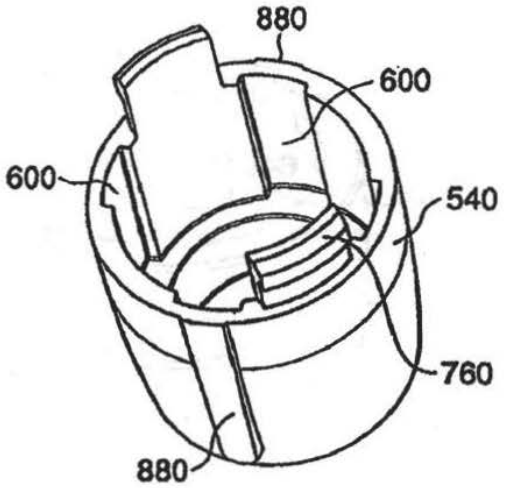

Fig. 22A

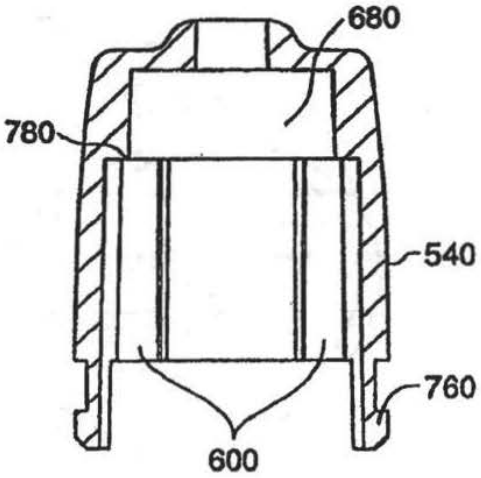

Fig. 22B

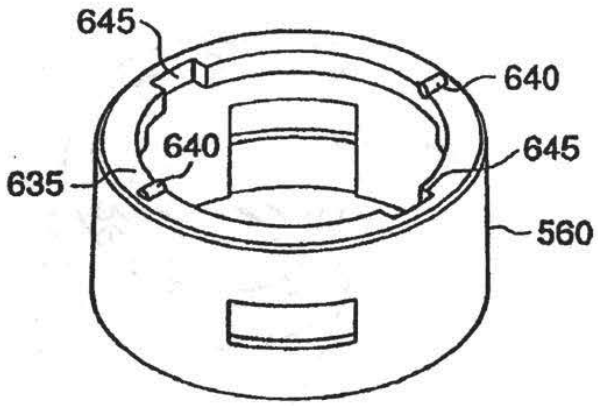

Fig. 23A

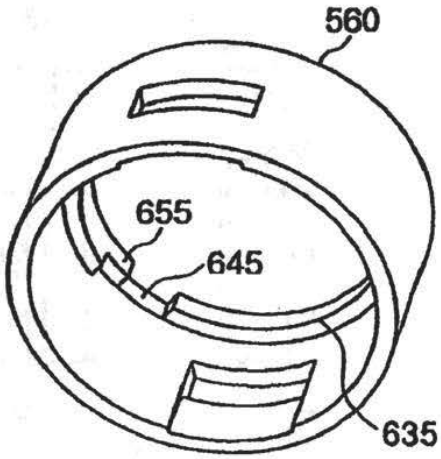

Fig. 23B

ANT-DEL00258765

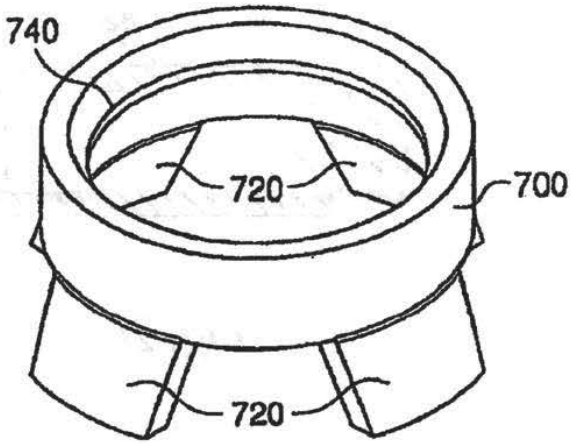

Fig. 24

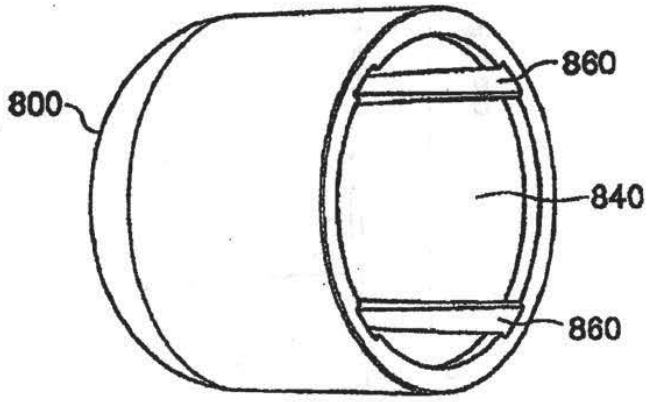

Fig. 25

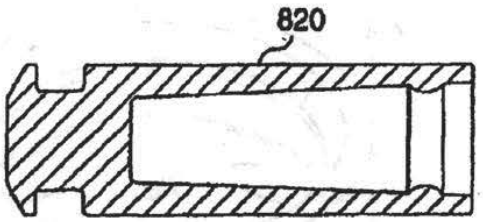

Fig. 26

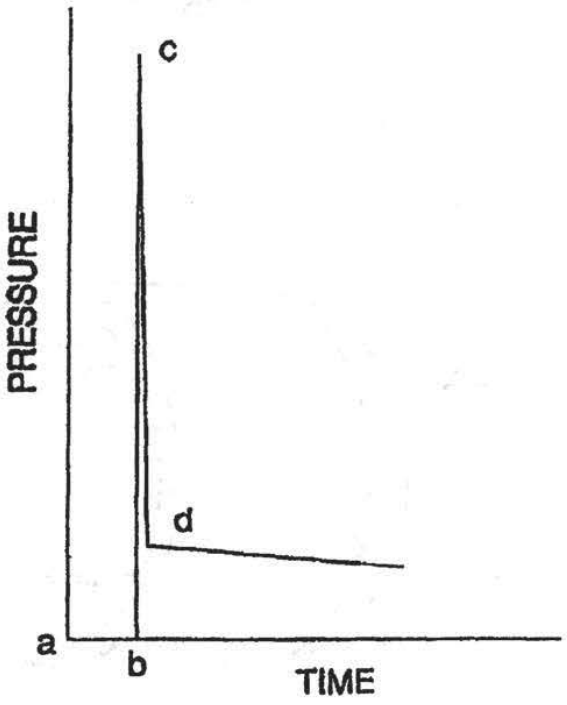

Fig. 27

NEEDLE ASSISTED JET INJECTOR

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a division of U.S. application Ser. No. 10/861,429, filed Jun. 7, 2004, which is a division of U.S. application Ser. No. 09/779,603, filed Feb. 9, 2001, now U.S. Pat. No. 6,746,429, which is a continuation of International Patent Application No. PCT/US99/17946, filed Aug. 10, 1999, which claims priority to U.S. Provisional Application No. 60/096,464, filed on Aug. 11, 1998. The entire content of these applications is expressly incorporated herein by reference thereto.

FIELD OF THE INVENTION

The present invention is directed to a device for delivery of medicament, and in particular to a jet injector with a short needle to reduce the pressure at which the jet injector must eject the medicament for proper delivery.

BACKGROUND OF THE INVENTION

A wide variety of needleless injectors are known in the art. Examples of such injectors include those described in U.S. Pat. No. 5,599,302 issued to Lilley et al., U.S. Pat. No. 5,062,830 to Dunlap, and U.S. Pat. No. 4,790,824 to Morrow et al. In general, these and similar injectors administer medication as a fine, high velocity jet delivered under sufficient pressure to enable the jet to pass through the skin.

As the skin is a tissue composed of several layers and the injector is applied to the external surface of the outermost layer, the delivery pressure must be high enough to penetrate all layers of the skin. The layers of skin include the epidermis, the outermost layer of skin, the dermis, and the subcutaneous region. The required delivery pressure is typically greater than approximately 4000 p.s.i. (27,579 kPa) (measured as the force of the fluid stream divided by the cross-sectional area of the fluid stream).

Although this pressure is readily achievable with most injectors, there are some circumstances in which delivery of medicament to the subcutaneous region under a reduced pressure is desirable. For example, drugs that require a specific molecular structural arrangement, such as a linear protein configuration, may be rendered ineffective due to shear forces caused by the delivery of the drug at high pressures that alter the structural arrangement of the drug. As it is more difficult to deliver a large volume of fluid at a high pressure compared to a small volume, using a lower pressure facilitates delivery of a larger volume of fluid. Furthermore, the lower pressure could make manufacturing an injector device less expensive. The lower pressure would also reduce adverse stresses on the device and result in a corresponding increased useable device lifetime. Moreover, the lower pressure would make jet injection compatible with medicament stored and delivered in glass ampules, which typically cannot withstand the pressure typically reached by jet injectors.

One of the advantages associated with jet injectors is the absence of a hypodermic needle. Given the aversion to needles possessed by some, the absence of a needle provides

a psychological benefit. Even devices that utilize conventional hypodermic needles have attempted to capitalize on this psychological benefit. For example, self-injectors or auto-injectors like the ones disclosed in U.S. Pat. Nos. 4,553,962, 4,378,015 and PCT International Publication numbers WO 95/29720, WO 97/14455 have retractable needles which are hidden until activation. Upon activation, the needle extends from the bottom of the device and penetrates the user's skin to deliver medicament. As none of these devices involves delivery of the medicament using jet injection, the medicament delivery location is limited by the length of the needle. For example, if delivery in the subcutaneous region is desired, the needle must be long enough to reach the subcutaneous region. Furthermore, as auto-injectors operate like syringes, the injection time is several seconds or longer. In contrast, jet injectors typically inject in fractions of a second.

U.S. Pat. No. 5,304,128 to Haber et al. describes a jet injecting syringe that uses a short needle to assist injection. The syringe uses a gas powered driven plunger to force medication through the syringe and out of the needle. The needle is retracted until the syringe is activated and then is extended to puncture the skin of the person injected. However, the needle remains extended after the syringe is used. The extended needle could lead to potential biohazards and safety concerns, such as accidental injections and spreading of diseases. Also, the gas powered plunger is both complicated and expensive to manufacture.

PCT Publication No. WO 99/03521 of Novo Nordisk discloses an undefined concept of "jet" injection. However, this publication does not teach one the details of the driving mechanism necessary to practice the concept.

PCT Publication No. WO 99/22790 of Elan Corporation teaches a needle assisted injector having a retractable shield that conceals the needle both before and after use of the injector. The disclosed injector has a driving mechanism that operates on pressure created by a chemical reaction. Because of this chemically operated driving mechanism, the injecting time for the injector is at least three seconds and more likely greater than five seconds. This relatively long injection time may create discomfort in the patient receiving the injection. Also, the needle may move during the lengthy injection and add to the patients discomfort.

Even with minimally invasive medical procedures, it is advantageous to maintain the time for the procedures at a minimum. Thus, there exists a need for a needle assisted jet injector that operates at relatively low pressure and that is capable of quickly delivering medicament. There also exists a need for such an injector having a retractable or concealed needle to prevent the medical hazards associated with exposed needles.

SUMMARY OF THE INVENTION

The present invention relates to a needle assisted jet injector. In one embodiment, the injection device includes a housing; a retractable injection-assisting needle at a distal end of the injector; a nozzle assembly defining a fluid chamber having an opening for slidingly receiving at least a portion of the needle and being removably associated with the housing; a plunger movable in the fluid chamber; a trigger assembly; and a force generating source operatively associated with the trigger assembly so that movement of the trigger assembly activates the energy source to move the plunger in a first direction to expel a fluid from the fluid chamber. The retractable injection-assisting needle has a needle tip located at a distal end of the needle with at least a portion configured and dimensioned to slide through the nozzle assembly opening; a

discharge channel within the needle tip and terminating in an orifice through which the fluid is expelled; a body portion to direct fluid towards the discharge channel; a plunger receptor configured and dimensioned to receive at least a portion of the plunger; and a retraction element operatively associated with the needle and disposed substantially within the nozzle assembly. The needle is located within the nozzle assembly in a retracted position prior to activation of the force generating source. Movement of the plunger in the first direction upon activation of the energy source results in at least a portion of the needle tip extending beyond the nozzle assembly opening to a needle insertion point and expelling the fluid through the needle tip and past the needle insertion point to a needle injection site. The needle insertion point is located at the needle tip, and the needle injection site is distal to the needle tip. The retraction element returns the needle tip to the retracted position after activation of the energy source.

The retraction element may be a resilient O-ring, a spring, or a flexible membrane which moves to allow extension of the needle tip beyond the nozzle assembly opening and then returns to its original position to return the needle tip to its retracted position. The needle body can have an exterior surface which includes a ridge or recess for accommodating the retraction element. A shoulder can be disposed between the needle tip and the needle body for accommodating the retraction element. Preferably, the needle tip, when extended, has a length of approximately 1-5 mm.

In a preferred embodiment, the jet injector includes a housing having distal and proximal ends; a fluid chamber having a seal at one end and located within the housing for holding at least about 0.02 ml to 3 ml of a medicament; an injection-assisting needle having an injecting end and a piercing end and coupled to the distal end of the housing; a plunger movable within the fluid chamber; a force generating source capable of providing sufficient force on the plunger to eject an amount up to about 3 ml of the medicament from the fluid chamber in less than 2.75 seconds; a needle guard located at the distal end of the housing for concealing the needle, the needle guard being moveable between a protecting position and an injecting position; and an activation element operatively associated with the needle guard. The needle is moveable between a medicament storing position and a medicament delivering position. When the needle is in the medicament storing position, it is isolated from the fluid chamber. When the needle is in the medicament delivering position, the piercing end punctures the seal to provide a fluid pathway from the fluid chamber through the needle. Retraction of the needle guard exposes the injecting end of the needle to an insertion point and activation of the force generating source moves the plunger to expel medicament from the fluid chamber and thereby eject the amount of the medicament through the injecting end of the needle and past the needle insertion point to an injection site in less than 2.75 seconds. The needle insertion point is located at the injecting end of the needle, and the injection site is distal to the injecting end of the needle.

Retraction of the needle guard from the protecting position to the injecting position may activate the force generating source, which provides sufficient force to eject an amount of about 1 to 2 ml of the medicament in less than about 2.5 seconds. The jet injector can also include a locking element associated with the needle guard for locking the needle guard in the protecting position after activation of the injection device and after return of the needle guard to the protecting position, to prevent re-exposure of the needle.

The activation element can include an inner housing located inside the housing and having trigger projections for maintaining the plunger in an idle position; and a latch located inside the housing and circumferentially surrounding the inner housing, the latch being moveable between a firing position and an armed position. Retraction of the needle guard to the injecting position urges the latch toward the firing position, thereby releasing the trigger projections from the plunger and activating the injection device.

The jet injector can further include an elastomeric element, such as a spring element, that acts upon the needle guard and urges the needle guard toward the protecting position; wherein the elastomeric element returns the needle guard to the protecting position after the medicament has been ejected from the needle, thereby substantially re-enclosing the needle.

The needle is mounted on a needle holder operatively associated with the needle and the distal end of the housing, such that rotation of the needle holder places the needle in fluid communication with the fluid chamber. Preferably, the needle has a tip with a length of approximately 1-5 mm and the medicament is ejected at a pressure between around 100 to 1000 p.s.i. (689 to 6895 kPa) and at a rate of at least 0.40 ml/sec.

The jet injector may also include a removable safety cap operatively associated with the distal end of the injection device such that rotation of the safety cap imparts rotation on the needle. At least a portion of the housing is made of a transparent or translucent material for allowing viewing of the fluid chamber. The medicament is preferably ejected at a pressure between around 100 to 500 p.s.i. (689 to 3448 kPa) and at a rate of about 0.50 ml/sec so that about 1 ml of the medicament is ejected in about 2 seconds.

The fluid chamber may comprise an ampule having a distal end, a proximal end and an opening in each of the distal and proximal ends; a pierceable seal associated with the opening in the distal end; and a stopper located in the proximal end of the ampule for maintaining the medicament inside the ampule. An alternative fluid chamber may be used such that activation of the force generating source moves the pierceable seal towards the injection assisting needle to pierce the seal and moves the stopper to eject medicament from the injection assisting needle.

The present invention also relates to a method of delivering medicament to an injection site of a patient. The method includes the steps of extending a needle from a shield prior to inserting the needle into the needle insertion point, the shield initially concealing the needle; inserting the needle into the needle insertion point to a depth of less than 5 mm, with the needle being in fluid communication with a fluid chamber that contains at least about 0.02 to 2 ml of the medicament; and applying a force sufficient to eject the medicament from the fluid chamber and through the needle to deliver the medicament to the injection site in less than about 2.75 seconds. The needle insertion point is located more superficial than the injection site.

Preferably, the initial pressing of the shield against the injection site causes activation of the energy mechanism and may establish fluid communication between the needle and the fluid chamber. An additional step includes retracting the needle into the shield after the desired amount of medicament has been delivered to the injection site and wherein the applied force for injecting the medicament is sufficient to eject an amount of about 1 to 2 ml of the medicament in less than about 2.5 seconds. The needle has a length of approximately 1-5 mm and the medicament is ejected at a at a pressure between around 100 to 1000 p.s.i. (689 to 6895 kPa) and at a rate of at least 0.40 ml/sec. Preferably, the medicament is ejected at a pressure between around 100 to 500 p.s.i. (689 to

3448 kPa) and at a rate of about 0.50 ml/sec so that about 1 ml of the medicament is ejected in about 2 seconds.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a cross-sectional view of a needle assisted jet injector according to the present invention;

FIG. **2** is a cross-sectional view of the needle on the jet injector of FIG. **1**;

FIG. **3** is a perspective view of the needle of FIG. **2**;

FIG. **4** is an enlarged cross-sectional view of the jet injector of FIG. **1** with the needle in the retracted position;

FIG. **5** is an enlarged cross-sectional view of the jet injector of FIG. **1** with the needle in the extended position;

FIG. **6** is a perspective view of a second embodiment of the needle according to the present invention;

FIG. **7** is a partial cross-sectional view of a jet injector according to the present invention with the needle of FIG. **6** in the retracted position;

FIG. **8** is a partial cross-sectional view of a jet injector according to the present invention with the needle of FIG. **6** in the extended position;

FIG. **9** is a cross-sectional view of another embodiment of the present invention with a flexible member as the retraction element and the needle in the retracted position;

FIG. **10** is a cross-sectional view of the embodiment of FIG. **9** with the needle in the extended position;

FIG. **11** is a cross-sectional view of a two piece nozzle assembly having a fixed needle;

FIG. **12** is a cross-sectional view of another embodiment of a two piece nozzle assembly having a fixed needle;

FIG. **13** is a cross-sectional view of another embodiment of a two piece nozzle assembly having a fixed needle;

FIG. **14a** is a cross-sectional view of a needle assisted jet injector according to a preferred embodiment of the present invention;

FIG. **14b** is a cross-sectional view of the needle assisted jet injector of FIG. **14a** taken along a plane perpendicular to that of FIG. **14a**;

FIG. **15** is a perspective view of the outer housing of the needle assisted jet injector of FIGS. **14a** and **14b**;

FIG. **16** is a perspective view of the inner housing of the injector of FIGS. **14a** and **14b**;

FIG. **17** is an elevational view of the ram of the injector of FIGS. **14a** and **14b**;

FIG. **18a** is perspective view of the latch assembly of FIGS. **14a** and **14b**;

FIG. **18b** is a cross-sectional view of the latch assembly of FIGS. **14a** and **14b** taken along line A-A of FIG. **18a**;

FIG. **19** is a perspective view of the needle holder of FIGS. **14a** and **14b**;

FIG. **20a** is a cross-sectional view of the cartridge assembly of FIGS. **14a** and **14b**;

FIG. **20b** is a cross-sectional view of an alternative embodiment of the cartridge assembly of FIGS. **14a** and **14b**;

FIG. **21a** is a cross-sectional view of the needle assembly of FIGS. **14a** and **14b**;

FIG. **21b** is a cross-sectional view of the injecting needle of FIGS. **14a** and **14b**;

FIG. **22a** is a perspective view of the needle guard of FIGS. **14a** and **14b**;

FIG. **22b** is a cross-sectional view of the needle guard of FIGS. **14a** and **14b** taken along line A-A of FIG. **22a**;

FIG. **23a** is a perspective view of the needle guard cap of FIGS. **14a** and **14b**;

FIG. **23b** is a perspective view of the needle guard cap of FIGS. **14a** and **14b**;

FIG. **24** is a perspective view of the locking ring of FIGS. **14a** and **14b**;

FIG. **25** is a perspective view of the safety cap of FIGS. **14a** and **14b**;

FIG. **26** is a cross-sectional view of the needle cap of FIGS. **14a** and **14b**;

FIG. **27** is a schematic expressing a pressure-time curve for a jet injector.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

For convenience, the same or equivalent elements of the invention of embodiments illustrated in the drawings have been identified with the same reference numerals. Further, in the description that follows, any reference to either orientation or direction is intended primarily for the convenience of description and is not intended in any way to limit the scope of the present invention thereto.

As shown in FIG. **1**, a jet injector **10** according to the present invention comprises a nozzle assembly **12** attached to a housing **14**. As used in this application, the term jet injection means a particular class of injector that injects medicament by creating a high-speed jet of the medicament that penetrates the tissue of the patient to a distance beyond the exit of the injector. Also, the term distal shall designate the end or direction toward the front of jet injector **10**. The term proximal shall designate the end or direction toward the rear of the injector. The term longitudinal designates an axis connecting nozzle assembly **12** to jet injector **10**, and the term transverse designates a direction substantially perpendicular to the longitudinal direction including arcs along the surface of jet injector **10**, or nozzle assembly **12**.

Nozzle assembly **12** can be threadably connected to housing **14** such that it can be readily attached and detached. Alternatively, other known structures for mounting or attaching two components can be utilized as well to detachably mate nozzle assembly **12** to housing **14**. In this manner, injector **10** can be reused with various nozzle assemblies that may contain different medications of different doses either together or at different times. For instance, nozzle assembly **12** can be prefilled with medication and disposed of after each use. Further, a medication filling device such as a coupling device can be used to fill the fluid chamber with medication. U.S. Pat. No. 5,769,138 to Sadowski et al., the disclosure of which is herein incorporated by reference, is directed to such a coupling device.

A trigger assembly **16** is located at the proximal end of housing **14**. Trigger assembly **16** activates and triggers an energy source or force generating means **18** which forces medicament out of nozzle assembly **12**. Energy source **18** can be a coil spring, a gas spring, or a gas propellant.

According to a first embodiment of the present invention, nozzle assembly **12** has an injection assisting needle **20** movable within nozzle assembly **12**. Needle **20** will be discussed in detail after first describing the other components of injector **10**. The nozzle assembly **12** includes a nozzle member **22** having an opening **24** at the distal end, preferably having a diameter of about 0.04-0.4 inches (1.016 mm to 10.160 mm) or any other suitable diameter that would allow for the introduction of injection assisting needle **20** therein. Nozzle member **22** includes a cylindrical fluid chamber **26** terminating at the distal end in a right circular cone **28**. Cone **28** can be a convex cone (as shown), a right circular cone, or any other suitable configuration. A plunger **30** having a pressure wall contoured to cone **28** is positioned to slide within fluid chamber **26**. Plunger **30** can include sealing means such as one or

more O-rings or the like (not shown) that are formed around its outer periphery to provide a seal, or the plunger itself can be a seal, as described in U.S. Pat. No. 5,062,830, the disclosure of which is incorporated herein by reference. The plunger can also include additional sealing means at spaced intervals to provide a better seal.

Plunger **30** is connected to a ram **32** which in turn is connected to energy source **18**. Alternatively, ram **32** can be integrally formed with an energy mechanism if desired. An inertia mass **34** is connected to or integrally formed with ram **32** near the end of ram **32** closest to plunger **30**. Inertia mass **34** can be removably connected to ram **32** such that the mass can be adjusted to accommodate different types of injections, taking into consideration, for instance, the viscosity of the medication, the initial pressure build up desired, the strength of energy source **18**, and the depth of injection penetration, etc. Inertia mass **34** cooperates with ram retainer **36** to limit the distance that ram **32** can travel toward nozzle assembly **12**. One important safety aspect of this feature is that ram **32** cannot become a dangerous projectile if injector **10** is fired when nozzle assembly **12** is not present.

Trigger assembly **16** includes a trigger extension **38** having a trigger engaging notch **40**. Trigger extension **38** is attached to the end of ram **32**, for example, by a threaded engagement. Trigger assembly **16** also comprises a latch housing sleeve **42** fixedly attached to an actuating mechanism **44**. Actuating mechanism **44** is shown as a threaded coupling that operates by rotation movement. Latch housing sleeve **42** has a throughbore dimensioned to allow passage of trigger extension **38**. Latch housing sleeve **42** further has a plurality of sidewall openings **46** dimensioned to allow passage of balls or ball bearings **48**. A tubular button **50** having one open end and a closed end is telescopingly positioned with latch housing sleeve **42** as shown. Button **50** has a circumferential or annular groove **52** formed on an inner wall **54** thereof to allow portions of the balls **48** to engage groove **52** when trigger assembly **16** is in the fired position, i.e., not engaged with trigger extension **38** (not shown). Balls **48** are positioned so that they are substantially flush with an inner side wall surface **56** of latch housing sleeve **42** to allow trigger extension **38** to pass through latch housing sleeve **42**. A latch ball retaining cup **58** is telescopingly positioned within button **50**. A compression spring **60** is positioned between the cup **58** and button **50** to bias button **50** and cup **58** away from each other in the axial direction.

The structure of injection assisting needle **20** is best seen in FIGS. **2** and **3**. Needle **20** has a plunger receptor **62** at the proximal end which is configured to accommodate plunger **30** as it slides within fluid chamber **26**. Although plunger receptor **62** can be of any shape conforming to the exterior profile of plunger **30**, it is preferably conical. A needle inner wall **64** is contoured to narrow like a funnel to a needle discharge channel **66** to accelerate the fluid as it is discharged. Needle discharge channel **66** extends to a discharge orifice **68** at the distal end of needle **20**. Needle discharge orifice **68** has a diameter of 0.004 to 0.012 inches (0.102 to 0.305 mm). Preferably, the diameter is 0.005 to 0.0075 inches (0.127 to 0.191 mm).

The outer periphery of needle **20** can be of varied geometries such that it fits within fluid chamber **26** of nozzle assembly **12**. Advantageously, needle **20** has a conical body section **70** which narrows gradually or tapers towards a cylindrical body section **72** of smaller circumference. Preferably, a shoulder **74** is positioned to separate a needle tip **76** from cylindrical body section **72**. Needle tip **76** is also cylindrical, but has a smaller circumference than cylindrical body section **72** such that needle tip **76** can fit within and extend through opening **24** of nozzle assembly **12**. However, cylindrical body section **72** of needle **20** has a circumference such that shoulder section **74**, existing at the transition between cylindrical body section **72** and needle tip **76**, prevents cylindrical body section **72** from existing within opening **24**. The length of needle tip **76** from its end to shoulder **74** is approximately 1 to 5 mm. Thus, needle tip **76** will penetrate the skin to a depth less than 5 mm. It should also be noted that although needle tip **76** is shown having a single beveled end at a 45° angle, needle tip **76** can have any shape that penetrates the skin.

As shown in FIGS. **4** and **5**, needle **20** is positioned coaxially and retractably within the distal end of fluid chamber **26** such that when injector **10** is fired, needle tip **76** extends out opening **24** of nozzle assembly **12** at a speed sufficient to penetrate the outer layer of skin. By inserting needle tip **76** to a depth less than 5 mm, typically only the epidermis of the skin is penetrated and the pressure needed to deliver the medicament to the desired region by jet injection is lower than that would otherwise be needed with needleless jet injection. While delivery of medicament by syringes and auto-injectors is limited by the length of the needle, the needle assisted jet injector according to the present invention delivers the medicament to a depth deeper than the length of the needle. This depth can include any region of the skin and beyond including intradermal, subcutaneous, and intramuscular.

To provide a seal between needle **20** and fluid chamber **26**, needle **20** includes a sealing means such as an O-ring **78** or the like formed around the outer periphery of needle **20** and accommodated by slot **80**. In an alternative embodiment shown in FIG. **6**, needle **120** itself is the seal. Thus, slot **80** is not needed. Needle **120** also differs from needle **20** in that cylindrical body section **72** is absent so that conical body section **70** terminates at shoulder **74**.

FIG. **5** illustrates injection assisting needle **20** in its extended position. Needle tip **76** extends beyond the distal end of nozzle assembly **12**. Shoulder **74** abuts the bored out inner section of nozzle opening **24** to prevent needle **20** from extending beyond needle tip **76**. A retraction element **82**, in this embodiment a spring, is compressed to provide a recoil force once the medicament is expelled so that needle tip **76** will retract back into nozzle opening **24**. Needle **20** preferably has a ridge **84**, the distal surface of which provides an annular area for the compression of retraction element **82**. Alternatively, a washer can be used instead of the ridge **84** to contain O-ring **78** and compress the retracting mechanism during operation.

FIGS. **7** and **8** show needle **120** of FIG. **6** with nozzle assembly **12** in which retraction element **82** is a resilient O-ring or other like material known to those skilled in the art. When an O-ring is used as retraction element **82**, it can also act as a sealing mechanism, and for this reason the O-ring is preferred. The interior of needle **120** is similar to that of needle **20**. FIG. **7** illustrates needle **120** in the retracted condition, before expelling medicament, and FIG. **8** shows the extended condition during which medicament is expelled. Similar to embodiments previously described, this embodiment functions to extend the needle tip **76** beyond nozzle opening **24** and penetrate the outer layer of the patient's skin during operation. Also, similar to embodiments previously described, needle **120** also preferably has ridge **84** around the proximal end to provide a surface which compresses the resilient material when the injector is triggered.

Another embodiment of the present invention, shown in FIGS. **9** and **10**, uses a flexible member **86** as the retraction element. FIG. **9** illustrates the neutral condition before expelling the medicament. Flexible membrane **86** spans between walls **88** of nozzle assembly **12** which define fluid chamber **26**

for holding medicament. Similar to embodiments previously described, the distal end of nozzle walls **88** act to conceal needle tip **76** until the injector is fired. Needle **220** is attached to flexible membrane **86** by any conventional means known to those skilled in the art. Preferably, needle **220** is integrally attached to flexible membrane **86** with an adhesive. FIG. **10** shows needle **220** in its extended position where the needle tip **76** extends beyond the end of walls **88** such that needle tip **76** penetrates the outer layer of skin to allow injection and deliver of the medicine at reduced pressure.

Other embodiments of the present invention relate to injectors with a fixed needle, i.e. a non-retracting needle that permanently extends beyond the nozzle assembly. Both a one-piece and a two-piece nozzle assembly with a fixed needle can be used and are contemplated by this invention.

FIGS. **11** and **12** show embodiments of the present invention with a two piece nozzle assembly with a fixed needle **320**. A first section **90** of nozzle assembly **12** has needle **320** at the distal end and can either be attached internally or externally to a second section **92** to form nozzle assembly member **12**. Although any conventional attaching means can be used, such as solvent or adhesive bonding, FIG. **11** shows a preferable friction-fitting or snapping attaching means **94** for both internal and external attachment of first section **90** and second section **92**. FIG. **12** shows a preferable ultrasonic bonding means **96** of attachment. Although ultrasonic bonding features **96** can be placed at any location to attach the two pieces, preferably, the ultrasonic bonding features **96** are along the distal end at the interface between first and second sections **90**, **92** to facilitate ease of manufacturing.

Another embodiment of a multi-piece nozzle assembly with fixed needle **320** is shown in FIG. **13**. The nozzle assembly consists of nozzle member **22** having an opening **24** designed to receive a tubular insert to create fixed needle **320**. Although FIG. **13** shows a multi-piece nozzle assembly, fixed needle **320** can be made to be integral with nozzle assembly **12**.

FIG. **14a** and FIG. **14b** depict a preferred embodiment of the present invention having a retractable shield around the needle. An inner housing **25**, shown in FIG. **16**, snaps inside an outer housing **45**, using a pair of snaps **65** located on the inner housing **25**. The snaps **65** protrude through openings **85** in the outer housing **45**, shown in FIG. **15**, and maintain the inner housing **25** and the outer housing **45** in a fixed relationship with one another. Other techniques known in the art, such as gluing and welding, could be used to hold the inner housing **25** and outer housing **45** together.

The inner housing **25** has three trigger protrusions **100** extending from its distal end. These trigger protrusions **100** are shaped to mate with an annular recess **140** in ram **125** (FIG. **17**). Ram **125** is urged toward the distal end of the injector with a compression spring **240**, however other energizing devices capable of producing an injection of up to 2 ml in about 2.5 seconds or less could be used. These energizing sources typically include rubber elastomers and compressed gas cartridges. A latch **160**, shown in FIG. **18a**, is slidable inside the outer housing **45** and surrounds the inner housing **25**. The latch **160** has a barrel portion **180** at its distal end and a pair of extensions **200** at its proximal end. When the jet injector is ready to be fired, ridge **225** on the barrel portion **180**, shown in FIG. **18b**, contacts the trigger protrusions **100** and maintains them in the annular recess **140** in ram **125**, preventing the ram **125** from firing under the force of compression spring **240**.

A needle holder **260**, shown in FIG. **19**, mounts onto the inner housing **25** with right hand threads **280** and holds a cartridge assembly **300** inside the inner housing **25**. As best shown in FIG. **20a**, the cartridge assembly **300** consists of a glass ampule **320** having an opening **340** in its proximal end and a seal **360** on its distal end. The glass ampule **320** typically holds between 0.02 and 2 mL of a medicament **400**. Instead of glass, the ampule **320** can also be constructed of metal or other suitable materials known in the art. A rubber stopper **380** is slideable within the glass ampule **320** and seals the opening **340** in its proximal end of the glass ampule **320** so the medicament **400** stays inside the glass ampule **320**. The seal **360** on the distal end comprises a rubber seal **420** formed on the end of the ampule **320** by conventional techniques, such as an aluminum cap **440** having a hole in its end. The ram **125** extends into the opening **340** in the proximal end of the glass ampule **320** and abuts the rubber stopper **380**. To provide a visual indication of the device's status, at least a portion of the outer housing **45** is constructed of transparent or translucent material, so that the cartridge assembly **300** can be viewed by the user.

A needle assembly **460**, shown in FIG. **21**, consists of an injecting needle **480** glued inside a longitudinal pocket **500** in the needle hub **520**. Grooves or other surface treatment on the longitudinal pocket **500** and on the injecting needle **480** enhance bonding between the injecting needle **480** and the needle hub **520**. Alternatively, other known methods of fixing, such as molding, may be used to secure the injecting needle **480** to the needle hub **520**.

To allow for an appropriate injection time, the injecting needle **480** is of 27 gauge, however other gauges may be suitable for different applications. The length of the needle **480** that extends beyond the distal end of the needle hub **520**, and is used for injection, is preferably between 1 and 5 mm. As shown in FIG. **21b**, the injecting needle **480** preferably has a 30 point. This angle decreases the length of the bevel **481** and thereby increases the effective length of the lumen **483**. The increase in the effective length of the lumen **483** reduces the percentage of incomplete injections.

Needle assembly **460** is mounted to the needle holder **260**, and clockwise rotation of the needle holder **260** approximately one quarter of a turn threads it further into the inner housing **25** and forces the proximal end of the injecting needle **480** through rubber seal **420**, thereby creating the drug path.

A needle guard **540**, depicted in FIG. **22a**, is located at the distal end of the injecting device and conceals the injecting needle **480**. The needle guard **540** snaps together with the needle guard cap **560**, which is shown in FIGS. **23a** and **23b**. The needle guard cap **560** slides on extensions **200** of the latch **160**, thereby allowing the needle guard **540** to slide longitudinally on the distal end of the injector to expose the injecting needle **480**. Feet **580** at the end of extensions **200** prevent the needle guard cap **560** and consequently the needle guard **540** from sliding completely off the end of the device.

Recesses **600** in the needle guard **540** and corresponding bosses **620** on the needle holder **260** translate any rotation of the needle guard **540** into rotation of the needle holder **260**. Abutments **655** on the inner surface of the needle guard cap **560**, shown in FIG. **23b**, are positioned relative to the feet **580** of the latch **160** to inhibit counter-clockwise rotation of the needle holder **260**. This prevents the user from unscrewing the device and removing the cartridge assembly **300** from it.

The needle guard cap has a inner flange **635** with a pair of cutouts **645** therein. The cutouts **645** correspond to the pair of bosses **625** on the inner housing **25**. The flange **635** acts to prevent motion of the needle guard cap **560** and the needle guard **540** toward the proximal end of the device unless the cutouts **645** are rotated into alignment with the pair of bosses **625**. This acts as a safety feature to prevent accidental firing of

the injector. Alternatively, other known mechanisms, such as a removable safety strip can be used to prevent accidental firing of the injector.

A return spring **660** rests on the needle holder **260** and urges the needle guard **540** toward the distal end of the injector, thereby keeping the injecting needle **480** concealed. A pair of stops **640**, shown in FIG. **23**, extend from the needle guard cap **560** and are positioned relative to bosses **625** on the inner housing **25** such that the needle guard **540** and needle holder **260** cannot rotate clockwise under the force of return spring **660**.

Pressing the needle guard **540** toward the proximal end of the device causes the needle guard cap **560** to push the latch **160** longitudinally toward the proximal end of the device, thereby moving the ridge **225** on the barrel portion **180** of the latch **160** off the trigger protrusions **100** on the inner housing **25**. This allows the trigger protrusions **100** to flex out of the annular recess **140** in the ram **125**, thereby causing the ram **125** to fire under the force of compression spring **240**. When the ram **125** fires, it slides rubber stopper **380** in the glass ampule **320** toward the distal end of the device, causing the medicament **400** to flow through the drug path (created by turning the needle holder **260** clockwise one quarter turn prior to firing, as discussed above) and eject from the injecting needle **480**.

As depicted in FIG. **22b**, needle guard **540** has a pocket **680** located therein. A locking ring **700**, shown in FIG. **24**, sits in pocket **680** and prevents re-exposure of the injecting needle **480** after the device has been fired. Locking ring **700** has multiple splayed legs **720** and an undercut **740** that mates with extensions **760**, which protrude from the needle holder **260**. Upon depression of the needle guard **540** toward the proximal end of the device, extensions **760** engage the undercut **740** and become locked thereon. When the needle guard **540** returns to its original position, the locking ring **700** is pulled from pocket **680** in the needle guard **540** and splayed legs **720** expand radially outward. Upon an attempt to re-depress the needle guard **540**, splayed legs **720** catch shoulder **780** on the needle guard **540** and restrict further movement of the needle guard **540**, thereby preventing re-exposure of the injecting needle **480**.

The device also features a removable safety cap **800** that slides over the needle guard **540** and covers the device prior to its use. The safety cap **800** includes a needle cap **820** (FIG. **26**) connected thereto, the needle cap **820** forming a sterile barrier around the needle assembly **460**. As shown in FIG. **25**, the safety cap **800** has four longitudinal recesses **860** equally displaced about its inner surface **840**. These longitudinal recesses **860** are dimensioned to accept two or more bosses **880** located at corresponding locations on the needle guard **540**. Because of these two features, clockwise rotation of the safety cap **800** causes corresponding rotation of the needle guard **540** and the needle holder **260**. Thus, the user may turn the safety cap **800** clockwise one quarter turn, prior to removing it from the device, to create the drug path and prepare the device for injection.

The device of the preferred embodiment is operated by first turning the safety cap **800** clockwise one quarter of a turn, to create the drug path by inserting the proximal end of injecting needle **480** into the ampule **320**. Rotating the safety cap **800** also aligns the cutaways **645** in the safety cap **560** with the bosses **625** on the inner housing **25**, allowing the needle guard **540** to be depressed. Next the safety cap **800** and consequently the needle cap **820** are removed from the device. As the distal end of the device is pressed against the injection site, the needle guard **540** moves longitudinally toward the proximal end of the device and the injecting needle **480** enters the skin to a depth of between 1 and 5 mm. The movement of the needle guard **540** causes the ram **125** to fire and consequently between 0.02 and 2.0 ml of medicament **400** is forced out of the ampule **320** and through the drug path in under about 2.75 seconds. Once the device is removed from the injection site, the needle guard **540** returns to its original position under the force of return spring **660**, concealing the injecting needle **480**. The locking ring **700** locks the needle guard **540** in place to prevent re-exposure of the injecting needle **480**. Alternatively, a push button could be located at the proximal end of the device and be locked in an idle position. The movement of the needle guard **540** could unlock the push button and allow the user to depress it and consequently fire the device.

FIG. **20b** shows another embodiment of the cartridge assembly **302** of the preferred embodiment. The cartridge assembly **302** comprises a glass ampule **322** and a needle assembly **462** sealed on its distal end. A pierceable seal **422** is located in proximity to the proximal end of the injecting needle **482** and creates a barrier between the medicament **402** and the injecting needle **482**. A rubber stopper **382** is slideable within the glass ampule **322** and seals an opening **342** in its proximal end so the medicament **402** stays inside the glass ampule **322**. Upon firing of the injector, the ram **125** urges the rubber stopper **382** toward the distal end of the injector. Since the medicament **402** is an incompressible fluid, the pierceable seal **422** is forced onto the distal end of the injecting needle **482**, thereby breaking the barrier and creating the drug path. With this cartridge assembly **302**, no turning of the device is required to create the drug path, and the threads on the inner housing **25** and on the needle holder **260** can be replaced by known permanent fixing techniques, such as gluing or welding.

A significant advantage of the needle assisted jet injector according to the present invention is that it allows for a lower pressure to deliver the medicament at the desired rate. In this regard, administering an injection using either a fixed or retractable needle requires less energy and force than conventional jet injector devices. FIG. **27** shows a pressure-time curve for a jet injector. The peak pressure at point c is the pressure needed to penetrate the skin and point d and beyond is the pressure at which a jet stream of medicament is delivered. As shown in the chart below, needle assisted jet injectors do not need to achieve as high as peak pressure as conventional jet injectors because the outer layer of skin is penetrated by the needle.

Pressure and Time (sec.) to Inject 1 cc

Pressure	26 Gauge needle	27 Gauge needle
150 psi	2.1	4.2
200 psi	1.9	3.9
240 psi	1.7	3.3
375 psi	1.4	3.1

A lower peak pressure can be used to deliver the medicament to the desired region and still achieve a short injection time. It is also possible that a lower steady state pressure can be used to deliver the jet stream after the needle and the jet injection have reached the desired region.

Reduced operating pressure decreases the chances of glass ampule breakage. The chart below shows the statistical predictions of breakage for glass cartridges at different pressures, based on the Gaussian distribution of actual breakage rates at various pressures.

Breakage Rates for Glass Cartridges

Pressure (psi)	Breakage Rate
310	1.5×10^{-11}
412	1.0×10^{-9}

It can be seen that a relatively small increase in pressure (100 p.s.i. (689 kPa)) increases the breakage rate by two orders of magnitude. Thus, the reduced operating pressure of the needle assisted injection device of the present invention greatly reduces the risk of ampule breakage.

Experimentation has confirmed that the needle assisted injector according to the present invention can be operated using a lower generating energy source and still maintain the quality of the injection. Specifically, experimentation has shown that a higher percentage of successful injections can be achieved with a needle assisted jet injector having a needle that penetrates the skin to a depth of 1 mm and 20 lb. (89 N) force generating means as with a conventional needleless jet injectors having 55 lb. (2445 N) force generating means. Similar results have been achieved with needles that penetrate 1-3 mm and force generating sources providing 20 lbs. and 40 lbs. (89 to 178 N) of force.

Another advantage of the needle assisted jet injector according to the present invention, shown in the chart below, is the decreased injection time compared to syringes or auto-injectors.

Comparison of Operating Properties for Injection Devices

	Spring Force (Lbf.)	Dia. Of Fluid Chamber (inches)	Avg. Pressure (psi)	Volume of Injection (ml)	Injection Time (sec)
Jet Injector	110	0.233	2111	0.5	0.165
1st Needle Assisted Injector	30	0.352	227	0.5	<1
2nd Needle Assisted Injector	15	0.231	233	0.5	<1
Conventional Syringe	N/A	0.351	5	0.5	3-5

As previously discussed, auto-injectors and syringes have injection times of several seconds or more. During this injection time, the quality of the injection can be compromised due to any number of factors. For example, the patient could move the syringe or auto-injector prior to completion of the injection. Such movement could occur either accidentally or intentionally because of injection-related pain. In contrast, the needle assisted jet injector, like other jet injectors, can have an injection time of less than 1 second. The short injection time minimizes the possibility of compromising the quality of the injection.

While it is apparent that the illustrative embodiments of the invention herein disclosed fulfill the objectives stated above, it will be appreciated that numerous modifications and other embodiments may be devised by those skilled in the art. Therefore, it will be understood that the appended claims are intended to cover all such modifications and embodiments which come within the spirit and scope of the present invention.

What is claimed is:

1. A jet injection device, comprising:

a housing member having distal and proximal ends;

a fluid chamber within the housing member holding about between 0.02 ml and 3 ml of a medicament comprising fluid;

an injection-assisting needle disposed at the distal end of the housing member, having an injecting end, and having an association with the fluid chamber to provide a fluid pathway from the fluid chamber through the needle, the injecting end of the injection-assisting needle having an axial opening for ejection of the medicament;

a plunger movable within the fluid chamber; and

a force generating mechanical member within the housing member that is elastically-deformed so as to provide sufficient force to eject the medicament from the fluid chamber through the needle by jet injection in a high-speed jet that exits the injecting end of the needle through the axial opening thereof at a fluid pressure of about between 100 and 1000 p.s.i. to penetrate patient tissue to a distance through and axially beyond the insertion point to an injection site;

wherein the injecting end of the needle has a position extending from the housing member by a length selected for inserting into a patient such that the injecting end reaches a needle insertion point at a depth of up to about 5 mm below the surface of the patient's skin; and

wherein the device is further configured such that activation of the force generating mechanical member applies the generated force to the plunger to expel the medicament from the fluid chamber.

2. The jet injection device of claim **1**, wherein the injection site is subcutaneous.

3. The jet injection device of claim **1**, wherein the needle insertion point is at a depth of between about 1 mm and 5 mm.

4. The jet injection device of claim **1**, wherein the needle insertion point is at a depth of up to about 3 mm.

5. The jet injection device of claim **1**, wherein the force generating source and needle are configured such that the medicament is injected at a rate of at least 0.40 ml/sec upon activation of the force generating source.

6. The jet injection device of claim **1**, wherein the force generating source and needle are configured to inject the amount of the medicament to the injection site in less than about 2.75 seconds.

7. The jet injection device of claim **1**, wherein the force generating source and needle are configured to inject the medicament at a rate so that about 1 ml of the medicament is ejected in about 2 seconds.

8. The jet injection device of claim **1**, wherein the force generating source and needle are configured to apply to the medicament a pressure that reaches up to about 500 p.s.i.

9. The jet injection device of claim **8**, wherein the force generating source and needle are configured to apply to the medicament a pressure that reaches between about 150 and 375 p.s.i.

10. The jet injection device of claim **1**, wherein the axial opening of the needle injecting end has a diameter of about between 0.004 to 0.012 inches and the needle has a length sufficient for penetrating the skin to a depth of between about 1 mm and 5 mm.

11. The jet injection device of claim **1**, wherein the needle is a 26 to 27 gage needle.

12. The jet injection device of claim **1**, wherein the needle further comprises a proximal portion that has common axial cross-sectional dimensions with the injecting end and extends proximally into an injection device housing member in which

the fluid chamber is disposed during the ejection of the medicament, the proximal portion being longer than the injecting end.

13. The jet injection device of claim **12**, wherein the proximal portion and injecting end have substantially common and continuous inner and outer diameters.

14. The jet injection device of claim **1**, wherein the fluid chamber is made of glass.

15. The jet injection device of claim **1**, wherein the housing member has a concealing association with the needle, wherein the device is configured such that the needle injecting end is extendable from the housing member to allow the insertion to the needle insertion point.

16. The jet injection device of claim **15**, wherein the housing member comprises a needle shield located at the distal end of the housing member for concealing the needle, the needle shield being moveable between: a protecting position, in which the needle is disposed within the guard prior to activation, and an injecting position, in which the tip of the needle is exposed for insertion to the insertion point.

17. The jet injection device of claim **16**, further comprising an activation element operatively associated with the shield such that the activation element activates the force generating source upon retraction of the shield from the protecting position to the injection position.

18. The jet injection device of claim **1**, further comprising a retraction element configured for retracting the needle into the housing member after the medicament is ejected.

19. The jet injection device of claim **1**, wherein the housing member and needle are cooperatively associated to allow the insertion of the needle to the insertion point.

20. A jet injection device, comprising:

a housing member having distal and proximal ends;

a fluid chamber within the housing member for holding at least about 0.02 ml to 3 ml of a medicament;

an injection-assisting needle disposed at the distal end of the housing member, having an injecting end, and having an association with the fluid chamber to provide a fluid pathway from the fluid chamber through the needle, the injecting end of the injection-assisting needle having an axial opening for ejection of the medicament;

a plunger movable within the fluid chamber; and

a force generating source comprising a spring pre-compressed to provide sufficient force to eject the medicament from the fluid chamber through the needle by jet injection in a high-speed jet that exits the injecting end of the needle through the axial opening thereof at a pressure of about between 100 and 1000 p.s.i. so as to penetrate patient tissue to a distance through and axially beyond the insertion point to an injection site wherein the needle insertion point is located more superficially than the injection site;

wherein the injecting end of the needle has a position extending from the housing member by a length selected for inserting into a patient such that the injecting end reaches a needle insertion point at a depth of no more than about 5 mm below the surface of the patient's skin; and

wherein the force generating source is further configured such that activation of the force generating source applies the force of the pre-compressed spring to the plunger to expel the medicament from the fluid chamber.

21. The jet injection device of claim **1** wherein the fluid chamber comprises a frangible material and the force generating member comprises a pre-compressed spring.

22. The jet injection device of claim **1** wherein the fluid chamber comprises glass and the force generating member comprises a pre-compressed elastomer.

23. An injection device comprising:

an outer housing member having distal and proximal ends;

an inner housing member located within the outer housing member;

a cartridge assembly disposed within the inner housing member, the cartridge assembly comprising a medicament;

a plunger movable within the cartridge assembly;

a needle assembly comprising an injecting needle;

a needle guard, at least a portion of which is located within the distal end of the outer housing member, the needle guard having an orifice through which the injecting needle passes, and wherein the needle guard has an extended sliding position, a retracted position when the medicament is expelled from the cartridge assembly and an extended locked position to cover the needle after the medicament is expelled from the cartridge assembly;

a latch within the proximal end of the outer housing member; and

a spring within the proximal end of the outer housing member and in communication with the latch and in force communication with a ram which is in force communication with the plunger to expel medicament from the cartridge assembly through the injecting needle, wherein before the needle guard moves from the extended sliding position toward the retracted position, the spring is under a compression sufficient to provide a force to expel the medicament from the cartridge assembly and the latch retains the spring under the compression until the needle guard reaches the retracted position.

24. An injection device according to claim 23, wherein the injecting needle passes through the orifice before the medicament is expelled from the cartridge assembly.

25. An injection device according to claim 23, wherein the injection needle has an axial opening for ejection of the medicament.

26. An injection device according to claim 23, wherein the cartridge assembly is in fluid communication with the needle assembly.

27. An injection device according to claim 23, wherein at least a portion of the outer housing member comprises transparent material.

28. An injection device according to claim 23, further comprising a second spring located within the needle guard, wherein the second spring applies a force to urge the needle guard towards the distal end of the injector device to conceal the injecting needle before and after the medicament is expelled from the cartridge assembly.

29. An injection device according to claim 23, further comprising a locking mechanism to maintain the needle guard in the extended locked position.

30. An injection device according to claim 23, further comprising a removable safety cap located at the distal end of the housing and covers the needle guard.

31. An injection device comprising:

an outer housing member having distal and proximal ends;

an inner housing member located within the outer housing member;

a cartridge assembly disposed within the housing member, the cartridge assembly comprising a medicament;

a plunger movable within the cartridge assembly;

a needle assembly in fluid communication with the cartridge assembly and comprising an injecting needle;

a spring within the proximal end of the outer housing member in force communication with a ram which is in force communication with the plunger to expel medicament from the cartridge assembly through the injecting needle;

a latch within the proximal end of the outer housing member and in releasing communication with the spring;

a pushbutton located at the proximal end of the outer housing member and in activating communication with the latch;

a needle guard in communication with the pushbutton, at least a portion of the needle guard is located within the distal end of the outer housing member, the needle guard having an orifice through which the injecting needle passes, and wherein the needle guard has an extended sliding position, a retracted position when the medicament is expelled from the cartridge assembly and an extended locked position after the medicament is expelled from the cartridge assembly; and

wherein movement of the needle guard communicates with and unlocks the pushbutton to permit a user to manually fire the injection device by depressing the pushbutton to activate the latch and release the spring; and

wherein before the needle guard moves from the extended sliding position toward the retracted position, the spring is under a compression sufficient to provide a force to expel the medicament from the cartridge assembly.

32. An injection device according to claim 31, wherein the injecting needle passes through the orifice before the medicament is expelled from the cartridge assembly.

33. An injection device according to claim 31, wherein the injection needle has an axial opening for ejection of the medicament.

34. An injection device according to claim 31, wherein at least a portion of the outer housing member comprises transparent material.

35. An injection device according to claim 31, further comprising a spring located within the needle guard, said spring applies a force to urge the needle guard towards the distal end of the injector device to conceal the injecting needle before and after the medicament is expelled from the cartridge assembly.

36. An injection device according to claim 31, further comprising a locking mechanism to maintain the needle guard in the extended locked position.

37. An injection device according to claim 31, further comprising a removable safety cap located at the distal end of the housing and covers the needle guard.

* * * * *

United States Court of Appeals for the Federal Circuit

Antares Pharma Inc. v. Medac Pharma Inc., 2014-1648

CERTIFICATE OF SERVICE

I, John C. Kruesi, Jr., being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

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On the **25th Day of July, 2014**, counsel has authorized me to electronically file the foregoing **Brief for Plaintiff-Appellant (Confidential and Non-Confidential versions)** with the Clerk of Court using the CM/ECF System, which will serve via e-mail notice of the filing to all counsel for the parties registered as CM/ECF users, including any of the following:

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Pursuant to an agreement between the parties, the confidential brief will be emailed to the above counsel on this date. Confidential paper copies will also be mailed to

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Upon acceptance by the Court of the e-filed document, six confidential paper copies will be filed with the Court, via Federal Express, within the time provided in the Court's rules.

July 25, 2014

/s/ John C. Kruesi, Jr.
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